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Supreme Court of the United States

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, M.D., on behalf of themselves and their patients seeking abortions,

Petitioners,

—v.—

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina; GOVERNOR OF SOUTH CAROLINA,

Respondents.

ON PETITION FOR A *WRIT OF CERTIORARI* TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions,

Plaintiffs-Appellees,

v. No. 99-1319

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina,

Defendants-Appellants,

GOVERNOR OF SOUTH CAROLINA,

Defendant.

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions,

Plaintiffs-Appellees,

v. No. 99-1710

Governor of South Carolina,

Defendant-Appellant,

and

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M.

CONDON, in his official capacity as Attorney General of the State of South Carolina,

Defendants.

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions,

Plaintiffs-Appellees,

v. No. 99-1725

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina,

Defendants-Appellants,

GOVERNOR OF SOUTH CAROLINA,

Defendant.

Appeals from the United States District Court for the District of South Carolina, at Greenville. William B. Traxler, Jr., District Judge. (CA-96-1898-6-21)

Argued: January 27, 2000

Decided: August 15, 2000

Before NIEMEYER, Circuit Judge, HAMILTON, Senior Circuit Judge, and Frederic N. SMALKIN, United States District Judge for the District of Maryland, sitting by designation.

Reversed by published opinion. Judge Niemeyer wrote the opinion, in which Judge Smalkin joined. Senior Judge Hamilton wrote a dissenting opinion.

COUNSEL

ARGUED: Floyd Matlock Elliott, HAYNSWORTH, MARION, MCKAY & GUERARD, L.L.P., Greenville, South Carolina, for Appellants. Bonnie Scott Jones, THE CENTER FOR REPRODUCTIVE LAW & POLICY, New York, New York, for Appellees. **ON BRIEF**: George Dewey Oxner, Jr., Boyd Benjamin Nicholson, Jr., HAYNSWORTH, MARION, MCKAY & GUERARD, L.L.P., Greenville, South Carolina; Nancy Staats Layman, Legal Division, DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, Columbia, South Carolina; Charles Molony Condon, James Emory Smith, Jr., OFFICE OF THE ATTORNEY GENERAL, Columbia, South Carolina; Charles E. Carpenter, Jr., Donald V. Richardson, III, S. Elizabeth Brosnan, RICHARDSON, PLOWDEN, CARPENTER & ROBINSON, P.A., Columbia, South Carolina, for Appellants. Randall Hiller, Greenville, South Carolina, for Appellees.

OPINION

NIEMEYER, Circuit Judge:

This case presents the important question of whether South Carolina's regulation establishing standards for licensing abortion clinics -- Regulation 61-12 of the South Carolina Department of Health and Environmental Control,

S.C. Code Ann. Regs. 61-12 (eff. June 28, 1996) -- violates the Due Process Clause and the Equal Protection Clause of the Fourteenth Amendment by placing an undue burden on women's decisions to seek abortions and by distinguishing between clinics that perform a specified number of abortions and those that do not. Two abortion clinics and an abortion provider filed this action, on behalf of themselves and their patients, facially challenging the constitutionality of the Regulation. The district court concluded that the Regulation violated both of these clauses of the Fourteenth Amendment, declared the Regulation "invalid," and enjoined its enforcement.

As amplified herein, we reverse this decision and uphold the constitutionality of Regulation 61-12 because (1) the Regulation serves a valid state interest and is little more than a codification of national medical- and abortion-association recommendations designed to ensure the health and appropriate care of women seeking abortions; (2) the Regulation does not "strike at the [abortion] right itself," *Planned Parenthood v. Casey*, 505 U.S. 833, 874 (1992) (joint opinion of O'Connor, Kennedy, and Souter, JJ.); (3) the increased costs of abortions caused by implementation of the Regulation, while speculative, are even yet modest and have not been shown to burden the ability of a woman to make the decision to have an abortion; and (4) abortion clinics may rationally be regulated as a class while other clinics or medical practices are not.

I

Prior to 1995, South Carolina regulated clinics at which second- trimester abortions were performed. *See* S.C. Code Ann. §§ 44-41-20(b), -70(b) (Law. Co-op.1985); S.C. Code Ann. Regs. 61-12 (1982) (entitled "Minimum Standards for Licensing Clinics Performing Abortions"). The regulation under this earlier statute contained chapters covering

abortion-clinic management, laboratory facilities and procedures, medical records and reports, clinic design and construction, and patient-care areas. *See* S.C. Code Ann. Regs. 61-12 (1982).

In 1995, the South Carolina legislature amended its statute to require any "facility in which any second trimester or five or more first trimester abortions are performed in a month" to be licensed as an abortion clinic by the Department of Health and Environmental Control ("DHEC"). S.C. Code Ann. §§ 44-41-10(C), -75(A) (West Supp.1999). In addition, it directed the DHEC to

> promulgate regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section.

Id. § 44-41-75(B). The DHEC responded by promulgating Regulation 61-12, effective June 28, 1996. *See* S.C. Code Ann. Regs. 61-12 (West Supp.1998) (hereinafter "Regulation 61-12" or "the Regulation").

In developing Regulation 61-12, the DHEC built on the preexisting version of its Regulation 61-12, as well as other DHEC regulations covering different types of healthcare facilities. The DHEC also consulted various medical standards and guidelines issued by medical care organizations, including groups dedicated to protecting abortion rights. These sources included: (1) Standards for Obstetric-Gynecologic Services (7th ed. 1995), issued by the American College of Obstetricians and Gynecologists ("the ACOG"); (2) Manual of Medical Standards and Guidelines

(1994), issued by Planned Parenthood, which the manual describes as encouraging affiliates "to develop abortion services if such a need exists in the community and resources are available for conducting a safe and effective program"; and (3) Standards for Abortion Care (1988), a set of standards, the "purpose" of which is "to promote high quality care for all women seeking abortions" and "serve as a useful resource for local and state agencies charged with safeguarding the public's health," issued by the National Abortion Federation, which the standards describe as "an organization specifically committed to the provision and accessibility of high quality abortion services for all women." The DHEC also reviewed abortion regulations from other states and referenced the Guidelines for Construction and Equipment of Hospital and Medical Facilities (1992-93), a document issued by the American Institute of Architects, which purports to provide "model standards" for "constructing and equipping new medical facility projects" and for "renovation or replacement work."

In addition to consulting established sources, the DHEC conducted public hearings, during which it received suggestions from the abortion clinics that are parties to this case, incorporating some of them in new Regulation 61-12. The new Regulation, entitled "Standards for Licensing Abortion Clinics," S.C. Code Ann. Regs. 61-12 (West Supp. 1998), contains ten parts which address a range of medical, safety, and administrative requirements:

Part I, "Definitions and Requirements for Licensure," defines an abortion clinic as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first-trimester abortions per month are performed." *Id.* § 101(B). It makes the operation of an abortion clinic without a license illegal. *See id.* § 102(A). It provides for periodic inspections, including at least one annually, and grants inspectors the authority to copy all documents required in the

course of inspections. *See id.* § 102(F). And it authorizes sanctions for non-compliance with the Regulation in the form of monetary penalties, as well as denial, suspension, or revocation of the license. *See id.* § 103.

Part II, "Administration and Management," requires every facility to formulate and review annually its policies and procedures. *See id.* § 201(B). It requires that each clinic maintain various administrative documents on file. *See id.* § 203. Every employee is required to complete in-service training and undergo a tuberculin skin test, *see id.* § 204(B), (F), and any employee diagnosed with a contagious disease is prohibited from performing certain work at the clinic, *see id.* § 204(D). It requires that every abortion be performed by a physician who is licensed by the State and requires that every clinic be affiliated with a physician who has admitting privileges at a local hospital. *See id.* § 205(C). A registered nurse must supervise all nursing care, and an ultrasound test may be conducted only by a person who has completed a course in ultrasonography. *See id.* § 205(D), (F). Each facility must display a copy of a statement specifying patients' rights, including the rights to dignity, privacy, and safety. *See id.* § 209.

Part III, "Patient Care," provides that each facility must have certain written patient-care policies and procedures to ensure professional and safe care and that no clinic may serve patients whose needs exceed the clinic's resources and capabilities. *See id.* § 301. Specified drugs and tools must be present, *see id.* § 303, and laboratory services must be available, either on site or through an arrangement with a laboratory, *see id.* § 304(A). A number of laboratory tests must be performed, including a urinalysis and testing for sexually transmitted diseases. *See id.* § 304(B), (C), (D). Staff at abortion clinics must have admitting privileges at a local hospital or have documented arrangements for emergency transfer to a hospital. *See id.* § 305(A). And

facilities that perform abortions beyond the 14th week of pregnancy must meet additional requirements. *See id.* § 309.

Part IV, "Medical Records and Reports," requires that every abortion clinic maintain and retain for ten years specified categories of information and requires that the documents be treated as confidential. *See id.* §§ 401, 402. Abortion clinics must report to the DHEC all abortions performed, any fetal deaths meeting certain criteria, and any accidents or incidents. *See id.* § 403.

Part V, "Functional Safety and Maintenance," requires written safety policies and procedures and a disaster-preparedness plan and sets standards for maintenance, requiring that facilities be kept in good repair. *See id.* §§ 501-503.

Part VI, "Infection Control and Sanitation," requires certain daily sterilization procedures, *see id.* § 602, mandates proper laundering of linen and washable goods, *see id.* § 603, and requires the facility to be kept neat, clean, and free of insects, *see id.* § 604. Garbage and waste are required to be disposed of in a manner designed to prevent transmission of disease. *See id.* § 605. Outside areas must be maintained so as to minimize fire hazards, havens for insects and rodents, and unsafe conditions from accumulations of water, ice, and snow. *See id.* § 606.

Part VII, "Fire Protection and Prevention," requires clinics to have particular firefighting equipment and an evacuation plan and to conduct fire drills and inspections. *See id.* § 701.

Part VIII, "Design and Construction," requires that each abortion clinic have facilities for the care of each patient that meet applicable design and construction laws. *See id.* §§ 801, 802. New buildings or additions must satisfy building

code requirements. *See id.* §§ 803, 804. Each facility must provide an adequate number of examination or procedure rooms, and each procedure room must have a suitable table and other equipment. *See id.* § 807(A), (B). Recovery areas must meet particular requirements and there must be a room for temporary storage of waste, as well as an area to accommodate sterilization procedures. *See id.* § 807(E), (F).

Part IX, "Prerequisites for Initial Licensure," sets forth the necessary documentation for obtaining a license from the DHEC and the certification that must be acquired for various physical items.

Finally, Part X states that conditions which arise and have not previously been addressed in the Regulation must be managed in accordance with the best practices as interpreted by the DHEC.

On June 27, 1996, one day before Regulation 61-12 was to take effect, the Greenville Women's Clinic, the Charleston Women's Medical Clinic, Inc., and Dr. William Lynn (collectively, the "abortion clinics") brought this action seeking a declaratory judgment that Regulation 61-12 is unconstitutional on its face because, among other things, it would violate their due process and equal protection rights, as well as those of their patients. They also sought an order enjoining enforcement of the Regulation and requesting attorneys fees and costs pursuant to 42 U.S.C. § 1988. The district court issued a temporary restraining order on June 19, 1996, which, by consent of the parties, was converted to a preliminary injunction. Finally, on February 5, 1999, the district court declared the Regulation invalid in its entirety.

The Greenville Women's Clinic, which has operated in Greenville, South Carolina, since 1978, has two licensed physicians who perform a combined average of more than 2,700 abortions per year. The physicians at the clinic

testified that even prior to the promulgation of Regulation 61-12, their clinic operated in substantial compliance with its requirements. They estimated that the additional cost of full compliance would be $22.68 per abortion. The district court found that, prior to the Regulation's promulgation, the cost of an abortion was between $325 and $480 if the abortion was not complicated and was performed during the first trimester. The court found that the additional cost of full compliance for Greenville Women's Clinic would be in the range of $23-$32 per abortion.

The Charleston Women's Medical Clinic, Inc., which has operated in Charleston, South Carolina, for about 28 years, performs, on average, more than 2,400 abortions per year. That clinic is operated by a licensed physician and a licensed practical nurse. The district court found that compliance with Regulation 61-12 by the Charleston Women's Medical Clinic would cost between $36 and $75 per abortion.

Dr. William Lynn, who is a licensed physician, has conducted his practice since 1980 from two locations -- in Beaufort, South Carolina (approximately 70 miles southwest of Charleston) and in Greenville, South Carolina. Dr. Lynn performs, on average, more than 900 abortions each year at the two sites. He testified that Regulation 61-12 would require him to undertake costly modifications to his Beaufort facility, and the district court found that his cost per abortion would increase by an amount between $116 and $368. The district court also concluded that the increased costs for Dr. Lynn's Beaufort facility would "likely force [Dr. Lynn] to cease performing abortions in his Beaufort office." *Greenville Women's Clinic v. Bryant*, 66 F. Supp. 2d 691, 717 (D.S.C.1999).

There was no direct evidence about how many other abortion clinics in South Carolina would be affected by the Regulation or about the extent of any such impact. No

woman who wanted an abortion or who claimed to be threatened by Regulation 61-12 was made a party to the action or testified before the district court, and no survey evidence of women in South Carolina was presented to demonstrate the likely effect that Regulation 61-12 would have on their decisions to obtain an abortion.

Following a bench trial, the district court concluded that the Regulation "serve[s] no legitimate state interest ... [g]iven the lack of evidence that the regulation will operate to improve the health care currently being received in this state." *Greenville Women's Clinic*, 66 F. Supp. 2d at 735. It continued that even if it did serve a valid purpose, the Regulation "places a substantial obstacle in the path of women seeking first trimester abortions and, thereby, imposes an undue burden on the woman's fundamental right to choose to undergo the procedure." *Id.* The undue burden, the court found, resulted from increased costs, delays in the ability to obtain abortions, decreased availability of abortion clinics, increased distances to travel to clinics, unlimited inspections of clinics, and compromises to patient confidentiality. *See id.* at 735-36. Accordingly, the court held that Regulation 61-12 violated women's Fourteenth Amendment due process rights. *See id.* at 736. The district court also ruled that the Regulation violated the abortion clinics' equal protection rights under either a strict scrutiny or a rational-basis standard of review because the Regulation "singles out physicians and clinics where abortions are performed regularly ... and imposes upon them requirements which are not imposed upon comparable procedures and not even upon all physicians who perform first trimester abortions." *Id.* at 742. Finally, the district court, acting under 42 U.S.C. § 1988, awarded the abortion clinics attorneys fees and costs in the amount of $324,040.

South Carolina appeals from the district court's judgment declaring Regulation 61-12 unconstitutional and enjoining

its enforcement and from the award of attorneys fees.

II

South Carolina contends first that the district court's due process analysis is supported by neither the record nor the law. It maintains that Regulation 61-12, which is based on national healthcare standards for abortions, is rationally related to protecting the health of women seeking abortions, "even if such regulations might have the incidental [e]ffect of causing the price to obtain an abortion to increase." South Carolina notes that the abortion clinics and their experts agree as to the appropriateness of the national standards incorporated in the Regulation, and the Greenville Women's Clinic, the largest of the plaintiffs, admitted that it was already in substantial compliance with virtually all of the Regulation's requirements. The State argues that to the extent any clinic does not comply with Regulation 61-12, compliance will improve the quality of medical care for women seeking abortions. South Carolina also argues that the evidence does not support the conclusion that the increased cost of an abortion would impose a substantial obstacle for women in South Carolina seeking abortions.

The abortion clinics respond that the Regulation does not further a valid state interest because (1) it creates costly and unnecessary requirements which are more likely to harm than to protect the health of abortion patients and (2) the DHEC's drafting process indicates that the DHEC was not concerned with protecting the health of such women. The clinics acknowledge that the DHEC may have relied on standards and guidelines of national medical groups, but they argue that these are just that -- standards and guidelines -- and are neither designed to serve as mandatory directives nor appropriate for that purpose. Finally, the abortion clinics contend that, in any event, Regulation 61-12 imposes an undue burden on women seeking abortions in South Carolina

because it would increase the price of abortions and force Dr. Lynn to cease performing abortions at his Beaufort facility.

The abortion clinics undertook a heavy burden in bringing a facial challenge to the constitutionality of Regulation 61-12. Because of the nature of facial challenges, they could not present the district court with a concrete factual circumstance -- a particular case or controversy -- to which to apply the Regulation. The clinics therefore must argue about the Regulation's impact generally and prospectively, the type of action typically undertaken by legislatures, not courts. Because a trial on a facial challenge can focus only on arbitrarily selected hypotheticals to which the Regulation might apply, a court is required to speculate about the Regulation's overall effect.

In this case, for example, the district court was not given -- and could not be given -- any data from South Carolina patients about the impact that particular costs had on their decision to seek an abortion. It was given only estimates by "experts." Accordingly, the impact of the Regulation in any given situation could only have been anticipated. Such anticipation, however, is generally not an appropriate basis on which to strike down statutes and regulations. *See Bowen v. Kendrick*, 487 U.S. 589, 612-13 (1988) (noting that "[i]t has not been the Court's practice" to strike down a statute on a facial challenge "in anticipation" of particular circumstances, even if the circumstances would amount to a "likelihood").

Because of the conceptual difficulties that attend to ruling on the constitutionality of a statute in the abstract, the Supreme Court has held that "[a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987);

see also Rust v. Sullivan, 500 U.S. 173, 183 (1991) (a facial challenge will fail if an act "can be construed in such a manner that [it] can be applied to a set of individuals without infringing upon constitutionally protected rights").

In *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), the Supreme Court ruled that a statute regulating abortion was invalid because "*in a large fraction of cases* in which [it] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Id.* at 895, (majority opinion) (emphasis added). Whether this holding displaced the *Salerno* standard for facial challenges in abortion cases has been the subject of considerable debate among the circuits. *Compare, e.g., Planned Parenthood v. Lawall*, 180 F.3d 1022, 1025-27 (9th Cir. 1999) (applying *Casey* standard to facial challenge to abortion restriction); *Women's Med. Prof'l Corp. v. Voinovich*, 130 F.3d 187, 193-96 (6th Cir. 1997) (same); *Jane L. v. Bangerter*, 102 F.3d 1112, 1116 (10th Cir. 1996) (same); *Planned Parenthood v. Miller*, 63 F.3d 1452, 1456-58 (8th Cir. 1995) (same); *Casey v. Planned Parenthood*, 14 F.3d 848, 863 n. 21 (3d Cir. 1994) (same), *with Barnes v. Moore*, 970 F.2d 12, 14 n. 2 (5th Cir. 1992) (per curiam) ("we do not interpret *Casey* as having overruled, *sub silentio*, longstanding Supreme Court precedent governing challenges to the facial constitutionality of statutes"); *see also Okpalobi v. Foster*, 190 F.3d 337, 354 (5th Cir. 1999) (noting that subsequent Fifth Circuit decisions were arguably inconsistent with application of the *Salerno* standard). This circuit, sitting en banc, acknowledged the uncertainty as to which standard applies but declined to resolve the issue. *See Planned Parenthood v. Camblos*, 155 F.3d 352, 358-59 & n. 1 (4th Cir. 1998) (en banc) ("Because we conclude ... that the [challenged abortion regulation] is facially constitutional under either the *Salerno* or the *Casey* standard, we need not, and do not, decide which of these two standards applies in facial challenges to abortion statutes"). Previously, a panel of this court had stated its

agreement with the Fifth Circuit position in *Barnes v. Moore*, observing that until the Supreme Court specifically overrules *Salerno* in the abortion-regulation context, "this Court is *bound* to apply the *Salerno* standard as it has been repeatedly applied in the context of other abortion regulations reviewed by the Supreme Court ... and in the context of challenges to legislative acts based on other constitutional grounds." *Manning v. Hunt*, 119 F.3d 254, 268 n. 4 (4th Cir. 1997) (emphasis added).

While we believe that the observation in *Manning* was part of the court's holding because application of *Salerno* was necessary to the ruling in that case and not dictum, we add the observation that the logic of the *Salerno* test is necessary to show deference to legislatures, particularly in light of the limitation imposed by Article III of the Constitution that the judiciary act only in cases and controversies. *See* U.S. Const. art. III, § 2. As we explain below, when the abortion clinics are confronted with *Salerno's* requirement that no set of circumstances exists under which Regulation 61-12 would be valid, they fail, if for no other reason, because the impact on the Greenville Women's Clinic is so modest. Even when we apply a less deferential standard than that articulated in *Salerno*, we nevertheless conclude in this case that the record provides no evidence from which to conclude that Regulation 61-12 would present a "substantial obstacle" to "a large fraction" of women in South Carolina who might seek an abortion at a clinic subject to Regulation 61-12. *Casey*, 505 U.S. at 895 (majority opinion).

The record contains evidence from several abortion providers, only one of which would be adversely affected in any significant way in providing abortion services, Dr. Lynn's Beaufort facility. Moreover, even for women in Beaufort, no evidence suggests that they could not go to the clinic in Charleston, some 70 miles away. Nor are we

provided with evidence of the impact that Regulation 61-12 would have on other South Carolina abortion clinics. Thus, inherent in our discussion of the impact that Regulation 61-12 would have on women's abortion rights is the inability to decide a concrete case; we must speculate about the impact on all relevant women to determine, under the *Casey* standard, whether a large fraction would encounter a substantial obstacle to their choice to seek an abortion, an analysis that the record simply does not permit. Thus, on the abortion clinics' failure to present evidence that would satisfy either of the possible standards, we fall back on the Regulation's presumptive constitutionality.

The principles of the abortion right itself are now well-established. Beginning in 1973, women were found to have a fundamental right grounded in the Fourteenth Amendment to end a pregnancy by aborting the life of the fetus. *See Roe v. Wade*, 410 U.S. 113, 153-56 (1973); *see also Maher v. Roe*, 432 U.S. 464, 474 (1977). The Court in *Roe* stated that the "right of privacy ... is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." *Roe*, 410 U.S. at 153.

Following *Roe*, which recognized that the abortion-decision right was not absolute but subject to some regulation by the states, the Supreme Court decided numerous cases that uncovered difficulties in applying *Roe* and created widespread confusion. Accordingly, in 1992, the Court in *Casey* reexamined *Roe* and restated the applicable principles. In *Casey*, the Court rejected the trimester framework of *Roe* and adopted a revised "undue burden" standard to apply to challenged abortion regulations. *Casey*, 505 U.S. at 872-74, (joint opinion of O'Connor, Kennedy, and Souter, JJ.). But it reaffirmed the "essential holding" of *Roe* -- that a woman has a constitutional right to "choose to have an abortion before viability and to obtain it without undue interference from the State." *Id.* at 846, (majority opinion). The scope of this

right, however, is framed by the State's "legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child." *Id.*

Most recently, in *Stenberg v. Carhart*, 530 U.S. ____, No. 99-830 (U.S. June 28, 2000), the Supreme Court reaffirmed the principles articulated in the joint opinion in *Casey* that: (1) a woman has a constitutional right "to choose to terminate her pregnancy" before viability of the fetus (2) any State law that imposes an "undue burden" on the woman's right to choose to terminate her pregnancy before fetal viability is unconstitutional; and (3) a State may regulate post-viability abortions "except where [they are] necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." 530 U.S. at ___, No. 99-830, slip op. at 2 (internal quotation marks and citations omitted).

In preserving the right of a woman to choose to have an abortion, the Court in *Casey* emphasized that the right is grounded in the liberty protected by the Fourteenth Amendment -- "[t]he controlling word in the cases before us is 'liberty.'" 505 U.S. at 846, (majority opinion); *see also id.* at 871, (joint opinion of O'Connor, Kennedy, and Souter, JJ.) ("The woman's right to terminate her pregnancy before viability is ... a component of liberty"). And the liberty so recognized is defined as the right of a woman *herself* -- not her husband, her parent, her doctor, or others -- to make the decision to have an abortion. *Id.* at 877, (joint opinion of O'Connor, Kennedy, and Souter, JJ.); *see also Stenberg*, 530 U.S. at ___, No. 99-830, slip op. at 27. Only when the State unduly burdens the ability of a woman to make the abortion decision "does the power of the State reach into the heart of the liberty protected by the Due Process Clause." *Casey*, 505 U.S. at 874 (joint opinion of O'Connor, Kennedy, and

Souter, JJ.).

Accordingly, to the extent that state regulations interfere with the woman's status as the ultimate decisionmaker or try to give the decision to someone other than the woman, the Court has invalidated them. *See Casey*, 505 U.S. at 887-98, (majority opinion) (striking down provision which required a physician performing an abortion on a married woman to obtain a statement from her indicating that she had notified her husband); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747, 767 (1986) (invalidating reporting requirements that "raise the specter of public exposure and harassment of women who choose to exercise their personal, intensely private, right, with their physician, to end their pregnancy"); *Bellotti v. Baird*, 443 U.S. 622, 643 (1979) (plurality opinion) (ruling that "if the State decides to require a pregnant minor to obtain one or both parents' consent to an abortion, it must also provide an alternative procedure whereby authorization for the abortion can be obtained" (footnote omitted)); *Planned Parenthood v. Danforth*, 428 U.S. 52, 74, (1976) (holding that "the State does not have the constitutional authority to give a third party an absolute, and possibly arbitrary, veto over the decision of the physician and his patient to terminate the patient's pregnancy").

On the other hand, state regulations that do not "reach into the heart" of the protected liberty do not violate the abortion-decision right. *Casey*, 505 U.S. at 874, (joint opinion of O'Connor, Kennedy, and Souter, JJ.). If a regulation serves a valid purpose -- "one not designed to strike at the right itself" -- the fact that it also has "the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Id.* One such valid purpose is a State's effort to "further the health or safety of a woman seeking an abortion." *Id.* at 878. Of course, if such health regulations

are unnecessary and have the "purpose or effect of presenting a substantial obstacle to a woman seeking an abortion," they will be found to "impose an undue burden on the right." *Id.*

In maintaining the distinction between state regulations that trammel the woman's right to choose to have an abortion -- those that impose an undue burden -- and those that merely have an incidental effect on the woman's decision, the Court has upheld, both before *Casey* and in *Casey*, various regulations, the costs and effects of which, while amounting to interference and intrusion, did not reach the core of the protected liberty. *See, e.g., Casey*, 505 U.S. at 886, (majority opinion) (upholding 24-hour waiting period although it would require a woman to make two visits to a doctor and increase the woman's exposure to abortion protestors); *id.* at 900-01, (upholding a recordkeeping and reporting provision that would increase the cost of some abortions); *Webster v. Reproductive Health Services*, 492 U.S. 490, 530 (1989) (O'Connor, J., concurring) (regulation requiring medical tests is constitutional where "the cost of examinations and tests that could usefully and prudently be performed ... would only marginally, if at all, increase the cost of an abortion"); *Planned Parenthood v. Ashcroft*, 462 U.S. 476, 490, 505 (1983) (upholding requirement for a pathology report that would impose a "small cost"). Only when the increased cost of abortion is prohibitive, essentially depriving women of the choice to have an abortion, has the Court invalidated regulations because they impose financial burdens. *See Akron v. Akron Ctr. for Reproductive Health*, 462 U.S. 416, 434-39 (1983) (holding unconstitutional a hospitalization requirement for certain abortions that more than doubled the cost of such abortions).

In the case before us, the South Carolina legislature directed the DHEC to promulgate regulations to address medical and safety aspects of providing abortions, as well as the recordkeeping and administrative practices of abortion

clinics. As directed, the DHEC drafted Regulation 61-12, building on the existing regulation, which applied to second-trimester abortion clinics, and consulting abortion regulations from other states. The DHEC also obtained and incorporated guidelines for outpatient facilities published by the American Institute of Architects, as well as standards and guidelines issued by the ACOG, Planned Parenthood, and the National Abortion Federation. Indeed, Regulation 61-12 largely tracks these medical standards and guidelines.

For example, the National Abortion Federation requires that all medical staff at member facilities be proficient in CPR, and the ACOG recommends specific plans for training personnel in CPR; Regulation 61-12 requires that all professional staff members be certified to perform CPR. *See* S.C. Code Ann. Regs. 61-12, § 204(C). The National Abortion Federation recommends that nursing-care providers receive training and orientation; the Regulation requires that each facility have and execute a written orientation program. *See id.* § 203(E). The ACOG recommends that physicians who perform abortions in their offices provide for prompt emergency treatment or hospitalization; the Regulation requires that each facility have an agreement with a doctor who has hospital admitting privileges. *See id.* § 205(C)(2). The National Abortion Federation recommends that a registered nurse or physician be responsible for a variety of components of the abortion procedure and requires that a registered nurse monitor recovering patients if general anesthesia has been used; the Regulation requires that a licensed registered nurse supervise nursing care. *See id.* § 205(D)(1). The National Abortion Federation requires that emergency drugs be kept on hand to treat seven specific conditions; the Regulation requires the availability of drugs to treat the exact same conditions. *See id.* § 303(A)(1). The National Abortion Federation states that testing for gonorrhea and chlamydia may be routinely provided; the Regulation requires testing for gonorrhea and chlamydia prior to each

abortion procedure. *See id.* § 304(C). The ACOG and the National Abortion Federation recommend that counseling be offered; the Regulation requires that arrangements be made for consultation. *See id.* § 307. The ACOG recommends retaining accurate medical records for each patient for the time period required by law; the Regulation requires that such records be retained for ten years. *See id.* § 401. The ACOG recommends specific plans and procedures for health and safety; the Regulation requires written policies and procedures for safety. *See id.* § 501. The ACOG recommends that the examining room contain facilities for sterilization; the Regulation sets out specific sterilization procedures. *See id.* § 602. The ACOG recommends procedures for disposing of contaminated waste supplies; the Regulation requires specific treatment of refuse and waste disposal. *See id.* § 605. The ACOG recommends procedures for proper use of fire equipment, and the National Abortion Federation recommends regular emergency drills; the Regulation requires firefighting equipment, alarm systems, and fire drills. *See id.* § 701. Planned Parenthood requires procedure rooms large enough to accommodate a stretcher or gurney, post- procedure recovery rooms, and dressing rooms, and the National Abortion Federation requires that the operating table be located in a room of adequate dimensions, illumination, and ventilation; the Regulation requires particular physical facilities at abortion clinics, such as procedure rooms with doors wide enough to accommodate a stretcher or wheelchair, recovery rooms, storage rooms, and a dressing room. *See id.* § 807. Planned Parenthood requires a battery-operated light source for emergency backup; the Regulation requires emergency power and lighting. *See id.* § 809.

The national standards promulgated by such medical groups as the ACOG, the National Abortion Federation, and Planned Parenthood indisputably aim to protect the health of women seeking abortions and one states explicitly that it is

intended to "serve as a useful resource for local and state agencies charged with safeguarding the public's health." National Abortion Federation, *Standards for Abortion Care* (1998). In relying upon such standards, the DHEC was appropriately focused on ensuring that abortion is "performed by medically competent personnel under conditions insuring maximum safety for the woman." *Akron*, 462 U.S. at 430 n.12, (quoting *Connecticut v. Menillo*, 423 U.S. 9, 11 (1975) (per curiam)). A witness for the abortion clinics testified that guidelines from organizations such as the ACOG and the National Abortion Federation "provide our best current assessment as to what is appropriate care." The witness explained that the ACOG has "only one interest," the healthcare of women, and if a doctor "deviate[s] from [the ACOG guidelines and standards] without a documented reason for [the] deviation, in a court of law it will be construed as malpractice." The witness recognized that the ACOG's guidelines "are commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients," and that the National Abortion Federation standards are "a distillate of extensive experience by highly skilled and experienced [abortion] providers."

This testimony on behalf of the abortion clinics should itself be sufficient to establish that Regulation 61-12 was reasonably designed to promote South Carolina's valid interest in women's health. But the DHEC was also entitled to draw support for its use of the standards from the observations made by the Supreme Court in abortion cases that the ACOG and National Abortion Federation standards indicate the "general medical utility" of a particular procedure. *Ashcroft*, 462 U.S. at 487 n.10; *see also Akron*, 462 U.S. at 435-37, (relying on changes in the ACOG standards, among others, to demonstrate lack of justification for hospitalization requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (upholding abortion regulations after

noting that "[o]n their face, the ... regulations appear to be generally compatible with accepted medical standards governing outpatient second-trimester abortions" (citing publications from groups including the ACOG)); *see also Stenberg*, 530 U.S. at ___, No. 99-830, slip op. at 18 (discussing the ACOG's "medical opinion" in analyzing the appropriateness of "[m]edical treatments and procedures"). Regulation 61-12 thus indisputably represents a reasonable attempt to further the health of abortion patients in South Carolina.

The abortion clinics argue that Regulation 61-12 exceeds and, in some cases, conflicts with the recommendations of these national groups. Further, they assert that the recommendations are just that -- recommendations -- and that requiring clinics to follow them will not necessarily safeguard or improve the health of abortion patients. The abortion clinics also note that some officials of these medical groups do not support mandatory compliance with the recommendations.

While Regulation 61-12 does in some instances exceed the standards of the ACOG, Planned Parenthood, and the National Abortion Federation, the bulk of the provisions comport with those guidelines, and any deviations are not substantial. Any contrary claim is belied by the abortion clinics' own testimony in this case. One of the doctors who owns the Greenville Women's Clinic, when asked whether Regulation 61-12 was "consistent with what you would consider to be the appropriate standards for abortion practice," responded that "[m]ost parts of the regulation we already comply with and do, but because it's good medical practice." Another abortion-clinic doctor testified that he complied with a number of the Regulation's provisions because "any doctor that's licensed by the State of South Carolina and any doctor that's completed an OB/GYN residency successfully would do that in the normal

operation." The fact that not all healthcare professionals agree with the adoption of each specific aspect of the Regulation is immaterial in light of South Carolina's "considerable discretion" in adopting licensing requirements aimed at the health of women seeking abortions. *Simopoulos*, 462 U.S. at 516, ("In view of its interest in protecting the health of its citizens, the State necessarily has considerable discretion in determining standards for the licensing of medical facilities").

Moreover, contrary to the district court's suggestion, *see Greenville Women's Clinic*, 66 F. Supp. 2d at 732, there is no requirement that a state refrain from regulating abortion facilities until a public-health problem manifests itself. In *Danforth*, for example, the Court upheld health measures that "may be helpful" and "can be useful." 428 U.S. at 80, 81. It cannot be gainsaid that a regulation incorporating the recommendations of the leading institutional authorities in the field of abortion provision aims to "further the health or safety of a woman seeking an abortion." *Casey*, 505 U.S. at 878, (joint opinion of O'Connor, Kennedy, and Souter, JJ.). Because South Carolina's Regulation 61-12 "appear[s] to be generally compatible with accepted medical standards governing ... abortions," *Simopoulos*, 462 U.S. at 517, we cannot reasonably conclude that the Regulation was not directed at promoting South Carolina's valid interest in a woman's health.

Even though Regulation 61-12 is directed at the valid objective of safeguarding the health of women seeking abortions, it may still be invalid if, in serving this objective, it unduly burdens "a woman's ability to make th[e] decision" to terminate a pregnancy. *Casey*, 505 U.S. at 874 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). Thus, having determined that Regulation 61-12 serves a valid purpose, we must still consider whether the cost imposed by the lawfully directed regulation presents "a substantial

obstacle to a woman seeking an abortion." *Id.* at 878. But a regulation is not rendered invalid simply because it makes it "more difficult or more expensive to procure an abortion," *id.* at 874, as "[a]ll abortion regulations interfere to some degree with a woman's ability to decide whether to terminate her pregnancy," *id.* at 875. In making this undue-burden assessment, the Supreme Court has repeatedly emphasized that the focus must be aimed more directly at *the ability to make a decision* to have an abortion as distinct from the *financial cost of procuring an abortion.*

The district court found that enforcement of Regulation 61-12 would increase the cost of obtaining an abortion in varying amounts, depending on the abortion clinic. The Greenville Women's Clinic, which purports to follow national medical standards for providing abortions, indicated that it substantially complies with the requirements of Regulation 61-12 and that full compliance would cost about $23. At the Charleston Women's Medical Clinic, the cost increase would be between $36 and $75. On the other hand, Dr. Lynn, who operates abortion clinics in Beaufort and Greenville, testified that he would have to make so many changes to his Beaufort facility that compliance would require him to cease providing abortions at that facility.

The record does not contain information indicating the manner in which Regulation 61-12 would actually affect any South Carolina woman's decision to seek an abortion. This is not due to a failure of proof but a problem inherent in conducting a facial challenge to the Regulation. The most that the parties could do in a preenforcement case is to speculate about the Regulation's impact. While they can reasonably forecast some cost increases, they can only surmise how any cost increase would affect a particular woman's decision to seek an abortion.

Even accepting the speculative figures relied upon by the

district court, we believe the court erred in concluding that at the two major clinics in this case -- the Greenville Women's Clinic and the Charleston Women's Medical clinic -- the impact from the expense of implementing Regulation 61-12 was unduly burdensome. While the $23-$75 increased cost per abortion due to compliance might make it "more difficult" and would make it "more expensive to procure an abortion," there is no evidence that it would impose an undue burden on "a woman's ability to make th[e] decision to have an abortion." *Casey*, 505 U.S. at 874, (joint opinion of O'Connor, Kennedy, and Souter, JJ.). As to Dr. Lynn's Beaufort clinic, no evidence suggests that women in Beaufort could not go to the clinic in Charleston, some 70 miles away.

Both *Casey* and pre-*Casey* decisions support the conclusion that predicted costs to raise medical standards do not amount to an undue burden on a woman's choice to obtain an abortion. In *Casey*, the Court considered a mandatory 24-hour waiting period, which the lower court had found would often cause "a delay of much more than a day because the waiting period requires that a woman seeking an abortion make at least two visits to the doctor" and would increase the exposure of women seeking abortions to the "harassment and hostility of anti-abortion protestors." 505 U.S. at 886 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). As a result, the lower court concluded that the State regulation would especially burden women with the fewest financial resources, who had to travel long distances, and who needed to explain their absences to their husbands or to others. *See id.* Yet the Supreme Court upheld the provision, stating that "on the record before us, *and in the context of this facial challenge*, we are not convinced that the 24-hour waiting period constitutes an undue burden." *Id.* at 887 (emphasis added). The *Casey* Court also upheld a recordkeeping and reporting provision, under which every facility that performed abortions had to file with the State a detailed report on every abortion, as well as quarterly

statistical data. Because this information was a "vital element of medical research," it could not "be said that the requirements serve no purpose other than to make abortions more difficult," even though the provision "might increase the cost of some abortions by a slight amount." *Id.* at 901 (majority opinion).

Similarly, in *Ashcroft*, the Court upheld a reporting requirement because, "[o]n its face and in effect," it was reasonably related to accepted medical standards and constituted common medical practice, 462 U.S. at 487, 505, even though the provision raised the cost of an abortion, *see id.* at 490. In contrast, the Court in *Akron* struck down a provision requiring that all second-trimester abortions be performed in a hospital because the evidence indicated that the cost of an abortion would double and second-trimester abortions were "rarely performed" in hospitals. 462 U.S. at 435.

In the case before us, as in *Casey*, the district court found that the Regulation would "caus[e] delays in the woman's financial ability to obtain an abortion" and would "increas[e] the distance a woman has to travel to obtain an abortion," thereby increasing the cost of an abortion. 66 F. Supp. 2d at 735. But again, in the context of a facial challenge and in the absence of any evidence in the record about how the cost would affect women's ability to make a decision, we conclude that the clinics have failed to demonstrate that the Regulation places any serious burden on a woman's ability to make an abortion decision.

Moreover, the increased costs claimed by the three abortion providers are particularly modest when one considers that their purpose is to protect the health of women seeking abortions. And there is no evidence that the ability of any woman to obtain an abortion or to decide to obtain an abortion would be frustrated by these particularized costs.

To conclude that any of the figures in this case would place an obstacle in the path of a woman's right to choose to have an abortion would necessitate the formulation of an arbitrary cost threshold beyond which a price increase may not pass. This would irrationally hamstring the State's effort to raise the standard of care in certain abortion clinics, the procedures and facilities of which do not adequately safeguard the health of their patients, simply because the clinics' performance falls so far below appropriate norms that the expense of upgrading their practices and equipment exceeds the arbitrarily defined amount.

Nor does it unduly burden a woman's right to decide to obtain an abortion that DHEC officials may inspect abortion clinics and copy necessary documents. Such inspections ensure compliance with healthcare standards, an end which the copying provision also furthers. *See Danforth*, 428 U.S. at 79, 81 (noting that a statute which allowed medical records to "be inspected and health data acquired by local, state, or national public health officers" did not have a "legally significant impact or consequence on the abortion decision or on the physician-patient relationship" (internal quotation marks omitted)). This is particularly so in view of the Regulation's requirement that "[a]ll records shall be treated as confidential," thereby respecting patients' privacy. *See id.* at 80 (noting that proper respect for patient's confidentiality was a factor in upholding reporting requirement); *cf. Whalen v. Roe*, 429 U.S. 589, 602 & n.29 (1977) ("disclosures of private medical information to ... public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient").

In short, South Carolina Regulation 61-12 serves a valid purpose, "one not designed to strike at the right itself," and it is not invalid simply because it has the incidental effect of making it modestly more difficult or more expensive to

procure an abortion. *Casey*, 505 U.S. (joint opinion of O'Connor, Kennedy, and Souter, JJ.).

III

South Carolina also contends that the district court erred in finding that Regulation 61-12 violates the Equal Protection Clause. The Regulation applies to facilities that perform one second-trimester abortion or five or more first-trimester abortions per month, but does not apply to facilities that perform fewer than five abortions per month or that perform no abortions at all. South Carolina argues that this classification is rationally related to its interests in regulating those facilities that perform abortions on a regular basis and notes that an abortion is recognized to be "a unique act fraught with consequences that go beyond mere medical complications."

The abortion clinics argue that because Regulation 61-12 "targets abortion providers and their patients, treats them differently than providers and patients of comparable medical procedures, and directly impacts the exercise of the right to abortion," we must review the Regulation under a standard of strict scrutiny. The abortion clinics contend that, under the strict-scrutiny standard, the Regulation cannot be upheld because it is not narrowly drawn to protect the health of women seeking abortions since their safety "is no more or less compelling than the safety of patients undergoing comparable procedures," which the State does not regulate.

At its essence, the Equal Protection Clause requires that "all persons similarly situated ... be treated alike." *Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 439 (1985); *Reed v. Reed*, 404 U.S. 71, 77 (1971). But this directive does not deny States "the power to treat different classes of persons in different ways." *Reed*, 404 U.S. at 75. Most regulations define groups to which they apply or to which benefits are

conferred and when any such group is defined, of necessity, the regulation favors or disadvantages other groups. *See Romer v. Evans*, 517 U.S. 620, 631 (1996). To withstand scrutiny under the Equal Protection Clause, therefore, a classification generally "must be reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to the object of the legislation." *Reed*, 404 U.S. at 76 (internal quotation marks and citation omitted). If, however, a regulation "impinges upon a fundamental right protected by the Constitution," *Perry Educ. Ass'n v. Perry Local Educators' Ass'n*, 460 U.S. 37, 54, (1983), or "operates to the peculiar disadvantage of a suspect class," *Massachusetts Bd. of Retirement v. Murgia*, 427 U.S. 307, 312 (1976), then the classification will be strictly scrutinized. While classifications in legislation ordinarily will be upheld against an equal protection challenge if "there is any reasonably conceivable state of facts that could provide a rational basis for the classification," *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 313 (1993), a regulation subject to strict scrutiny will be upheld only if it is justified by a compelling state interest, *see Roe*, 410 U.S. at 155.

In *Roe*, the abortion-decision right was found to be fundamental. 410 U.S. at 154-55, 162-63; *see also Maher v. Roe*, 432 U.S. 464, 474 (1977). But following *Casey*, that conclusion may be in doubt. The *Casey* decision does not refer to the abortion-decision right as fundamental and does not apply the traditional strict-scrutiny standard which protects fundamental rights. Rather, the Court adopted an "undue burden" standard. *Casey*, 505 U.S. at 874 (joint opinion of O'Connor, Kennedy, and Souter, JJ.); *see also Stenberg*, 530 U.S. at ___, No. 99-830, slip op. at 2. Indeed, any regulation that does not "strike at the [abortion] right itself" is assessed by asking not whether it serves a compelling state interest, but whether it "serves a *valid* purpose." *Casey*, 505 U.S. at 874 (joint opinion of

O'Connor, Kennedy, and Souter, JJ.) (emphasis added). The dissenting opinion by Chief Justice Rehnquist characterizes the joint opinion in *Casey* as follows:

> *Roe* decided that a woman had a fundamental right to an abortion. The joint opinion rejects that view. *Roe* decided that abortion regulations were subject to "strict scrutiny" and could be justified only in the light of "compelling State interests." The joint opinion rejects that view.

Id. at 954 (Rehnquist, C.J., dissenting).

But because we have concluded in Part II that South Carolina's Regulation 61-12 does not place an undue burden on a woman's ability to make an abortion decision, there is no need to resolve whether it remains a fundamental right for an equal protection analysis and thus requires application of the strict-scrutiny standard. *See Harris v. McRae*, 448 U.S. 297, 312, 322 (1980) (having concluded that a law restricting federal funding for abortion violated no constitutionally protected right, the Court held it was unnecessary to analyze whether the law infringed a fundamental right for equal protection purposes). And likewise the equal protection analysis of a regulation applicable to abortion clinics, and not other medical clinics, would not be conducted under the strict-scrutiny standard. No authority exists to support a conclusion that abortion clinicsor abortion providers have a fundamental liberty interest in performing abortions free from governmental regulation. *See, e.g., Birth Control Centers, Inc. v. Reizen*, 743 F.2d 352, 358 (6th Cir. 1984). Moreover, physicians as a group are not a suspect class. *See Attorney Gen. of New York v. Soto-Lopez*, 476 U.S. 898, 906 n.6 (1986) (recognizing suspect classifications to include those based on race, alienage, or national origin). Accordingly, because we are not considering a regulation that impinges on a fundamental right or that is directed at a

suspect class, we review South Carolina Regulation 61-12 under the Equal Protection Clause by applying a rational-basis standard to determine whether the Regulation's classification of physicians who perform one second-trimester abortion or five or more first-trimester abortions per month is *rationally* related to a valid governmental purpose.

The rationality of distinguishing between abortion services and other medical services when regulating physicians or women's healthcare has long been acknowledged by Supreme Court precedent. Beginning with *Roe* itself, the Court recognized not only the special medical interest of the women seeking abortions but also the State's interest in protecting prenatal life. *See* 410 U.S. at 150. The long stream of cases that followed *Roe* has only heightened an awareness that for purposes of regulation, abortion services are rationally distinct from other routine medical services, if for no other reason than the particular gravitas of the moral, psychological, and familial aspects of the abortion decision. As the Court in *Casey* observed:

> [T]he abortion decision ... is more than a philosophic exercise. Abortion is a unique act. It is an act fraught with consequences for others: for the woman who must live with the implications of her decision; for the persons who perform and assist in the procedure; for the spouse, family, and society which must confront the knowledge that these procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and, depending on one's beliefs, for the life or potential life that is aborted.

Casey, 505 U.S. at 852 (majority opinion). Similarly in *Harris*, the Supreme Court noted that it was rational for Congress to authorize federal reimbursement for medical necessities, but not for medically necessary abortions: "*Abortion is inherently different from other medical*

procedures, because no other procedure involves the purposeful termination of a potential life." 448 U.S. at 325 (emphasis added). And again in *Danforth*, the Court rejected the argument that "the State should not be able to impose any recordkeeping requirements [on abortion providers] that significantly differ from those imposed with respect to other, and comparable, medical or surgical procedures." 428 U.S. at 80-81. In the same case, the Court applied the identical analysis to uphold a provision requiring that a woman certify in writing that her consent to the abortion was freely given and not the result of coercion, "[d]espite the fact that apparently no other ... statute ... requires a patient's prior written consent to a surgical procedure." *Id.* at 66-67.

We thus conclude that South Carolina has a rational basis for regulating abortion clinics while not regulating other healthcare facilities. *See Williamson v. Lee Optical*, 348 U.S. 483, 489 (1955) ("The problem of legislative classification is a perennial one, admitting of no doctrinaire definition.... [T]he reform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind.... The legislature may select one phase of one field and apply a remedy there, neglecting the others").

The only question remaining is whether the line drawn by Regulation 61-12 at five abortions per month is rationally related to its purpose of protecting the health of abortion patients. When it is recognized that the State interest is in regulating those facilities that are in the business of providing abortions, drawing the line at those performing five abortions per month is rational. While anyone could say that it is just as rational to draw the line at ten abortions per month or three abortions per month, this type of line- drawing is typically a legislative function and is presumed valid. *See Murgia*, 427 U.S. at 314. Indeed, line-drawing of this type is not only typical of legislation, it is necessary. Thus, the Americans With Disabilities Act provides that the right to be free from

discrimination because of one's disability is granted to an employee of a company with 15 employees, but not to an employee of a company with only 14 employees. *See* 42 U.S.C. § 12111(5)(A). Similarly, Title VII of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, religion, sex, or national origin by employers with 15 or more employees, but not employers with 14 or fewer employees. *See* 42 U.S.C. § 2000e(b). The statute books are filled with similar examples. *See, e.g.*, the Family and Medical Leave Act, 29 U.S.C. § 2611(2) (giving rights only to employees employed 12 months or longer); the Comprehensive Crime Control Act of 1984, 18 U.S.C. § 3559(c)(1) (mandating a sentence of life imprisonment for persons convicted of three serious violent felonies). In a similar vein, South Carolina permits persons 16 years or older to obtain a driver's license, denying a license to persons 15 years or younger. *See* S.C. Code § 56-1-40; *see also* S.C. Const. art. XVII, § 14 (persons 18 years or older have "full legal rights and responsibilities"). In each of these instances, persons falling on one side of the line are treated differently from those on the other. But this result is inherent in legislation. Under rational-basis review, we need to determine only whether the line is drawn in a manner that reasonably furthers the legislative concern.

In this case, South Carolina elected to regulate the business of providing abortions and determined that five per month would distinguish the abortion clinic from the facility performing abortions incidental to another medical practice. The selection of this number is reasonably related to the State's legitimate interest in promoting and protecting the health of women visiting abortion clinics, and therefore the actual placement of the line is not a decision that the courts may second-guess. No more than the abortion regulations examined by the Supreme Court in *Danforth* and *Harris* does the South Carolina regulation before us contravene the limitations of the Equal Protection Clause.

IV

It is regrettable that our good colleague in dissent would rule on the basis that abortion is like any other simple medical procedure that is directed at injury or disease. Thought of in this way, it is understandable that he, like the district court, might find many of South Carolina's regulations unnecessary. Why have inspections, keep records, and minimize the medical risks for only the abortion procedure, when such a protocol is not mandated for comparable medical practices addressing injury and disease? But the importance of the deeply divided societal debate over the morality of abortion and the weight of the interests implicated by the decision to have an abortion can hardly be overstated. As humankind is the most gifted of living creatures and the mystery of human procreation remains one of life's most awesome events, so it follows that the deliberate interference with the process of human birth provokes unanswerable questions, unpredictable emotions, and unintended social and, often, personal consequences beyond simply the medical ones.

In adopting an array of regulations that treat the often relatively simple medical procedures of abortion more seriously than other medical procedures, South Carolina recognizes the importance of the abortion practice while yet permitting it to continue, as protected by the Supreme Court's cases on the subject. A woman in South Carolina who has determined to abort the life of a fetus can do so without significant interference from South Carolina's regulations and be assured thereby of a dignified and safe procedure. That these regulations impose a modest cost increase for increased medical safety and a modest compromise to privacy in the form of inspections and recordkeeping serves the complex public interests on the subject -- the interests expressed by both those who favor

abortion and those who oppose it.

Society's last word on this subject has not been spoken. But South Carolina's regulations incidental to the exercise of the abortion right should, in the meantime, be respected.

V

Because we reverse the district court's judgment finding Regulation 61-12 unconstitutional, we also reverse the district court's award of attorneys fees made under 42 U.S.C. § 1988 to the abortion clinics. The clinics are no longer prevailing parties. *See Alexander S. v. Boyd*, 113 F.3d 1373, 1388 (4th Cir. 1997); *Clark v. Township of Falls*, 890 F.2d 625, 626-27 (3d Cir. 1989).

REVERSED

HAMILTON, Senior Circuit Judge, dissenting:

After a six-day bench trial, the district judge, who presently is a judge on this court, wrote a ninety-four page decision setting forth innumerable factual findings which lead inexorably to the legal conclusions that South Carolina Code Annotated Regulation 61-12 violates both the Due Process and Equal Protection Clauses of the United States Constitution and that the unconstitutional portions of Regulation 61-12 are not severable from the constitutional portions. Cavalierly, the majority today sets aside this thorough and meticulous decision rendered by our esteemed colleague without identifying a single finding of fact made by him as being clearly erroneous. To accomplish this tour de force, the majority is compelled to set up and defeat a lack of evidence straw man. Unlike the majority, I believe the exhaustive and detailed factual findings made by the district judge amply support, more accurately compel, the decision

rendered by him. Because I am in complete agreement with the district judge's holdings that South Carolina Code Annotated Regulation 61-12 violates both the Due Process and Equal Protection Clauses of the United States Constitution and that the unconstitutional portions of Regulation 61-12 are not severable from the constitutional portions, I dissent.

I

The constitutional issues presented in this case were hotly contested by the parties at trial, with each side putting forth extensive evidence in support of their respective positions. Based on the evidence presented, the district court resolved many factual disputes by making detailed findings of fact. Because many of the district court's factual findings are completely ignored by the majority, I set forth below the procedural history and facts of this case.

A

Prior to 1995, the State of South Carolina only required licensing of physicians' offices or other facilities in which second trimester abortions were performed. *See* S.C. Code Ann. §§ 44-41-20(b), -70(b) (Law. Co-op. 1995). On January 3, 1995, the South Carolina legislature amended Chapter 41 of Title 44 to require licensing by the South Carolina Department of Health and Environmental Control (DHEC) of any non-hospital medical facility in which five or more first trimester abortions are performed in a month. *See id.* § 44-41-75(A) (West Supp. 1999). This legislation also required DHEC to promulgate regulations concerning "sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up

care necessary to carry out the purposes of this section." *Id.* § 44-41-75(B). Pursuant to this enabling legislation, DHEC promulgated a regulation, entitled "Standards For Licensing Abortion Clinics," *see* S.C. Code Ann. Regs. 61-12 (Regulation 61-12), which sets forth detailed requirements that an abortion clinic [1] must comply with in order to obtain and maintain a license to perform abortions.

On June 27, 1996, the day before Regulation 61-12 temporarily went into effect, Greenville Women's Clinic (GWC) and Charleston Women's Medical Clinic, Inc. (CWMC), two medical clinics which offer first trimester abortion services in South Carolina, and Dr. William Lynn (Dr. Lynn), a physician that owns and operates medical practices in Beaufort and Greenville, South Carolina, brought this action against Douglas Bryant (Bryant) as the Commissioner of DHEC, the Governor of the State of South Carolina, and the Attorney General of the State of South Carolina challenging the constitutionality of Regulation 61-12. On the same day, the plaintiffs filed a motion for a temporary restraining order, or, in the alternative, for a preliminary injunction.

On July 19, 1996, the district court granted the plaintiffs' motion for a temporary restraining order and enjoined the defendants from enforcing Regulation 61-12, pending a hearing on the issuance of a preliminary injunction. The district court never held a hearing on the issuance of a preliminary injunction because, prior to the hearing date, the parties agreed to continue the injunction pending a decision

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[1] An abortion clinic is defined as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first trimester abortions per month are performed." S.C. Code Ann. Regs. 61-12, § 101(B). Accordingly, the definition of abortion clinic includes any physician's office in which five or more first trimester abortions per month are performed.

by the district court on the merits.

Following a six day bench trial, the district court, on February 5, 1999, held that Regulation 61-12 was constitutionally infirm on due process and equal protection grounds. *See Greenville Women's Clinic v. Bryant*, 66 F. Supp. 2d 691, 724-43 (D.S.C. 1999). The district court also held that, in light of both South Carolina law and the text of Regulation 61-12, Regulation 61-12 was not subject to the doctrine of severability. *See id.* at 743-44. On April 13, 1999, the district court awarded the plaintiffs $324,040.61 in costs and attorneys' fees. Bryant and the Attorney General of South Carolina appeal both the district court's decision on the merits and the order awarding costs and attorneys' fees. The Governor of South Carolina appeals only the district court's order awarding costs and attorneys' fees.[2]

B

Located in Greenville, South Carolina, GWC provides gynecological services, including abortions through fourteen weeks of pregnancy measured from the pregnant woman's last menstrual period (lmp).[3] Drs. Terry Buffkin and Thomas Campbell, two physicians licensed to practice in South Carolina and board certified in obstetrics and gynecology, own and operate GWC. On average, GWC performs approximately 2,746 first trimester abortions per year.

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[2] Although the Governor of South Carolina appeals only the district court's order awarding costs and attorneys' fees, for ease of reference, I will refer to Bryant, the Governor of South Carolina, and the Attorney General of South Carolina as the defendants.

[3] Pregnancy is measured either from the date of a woman's lmp or from conception, which is generally considered to occur two weeks after a woman's lmp. Accordingly, eight weeks after the lmp is equivalent to six weeks from the date of conception. Under Regulation 61-12, the first trimester of pregnancy ends at fourteen weeks after the lmp. *See* S.C. Code Ann. Regs. 61-12, § 103(S).

Located in Charleston, South Carolina, CWMC also provides gynecological services, including abortions through 12.5 weeks of pregnancy measured from the pregnant woman's lmp. On average, CWMC performs 2,408 first trimester abortions per year.

Dr. Lynn owns and operates two medical practices, one in Beaufort, South Carolina, the other in Greenville, South Carolina. Dr. Lynn is licensed to practice medicine in South Carolina and is board certified in obstetrics and gynecology. As part of his practice, Dr. Lynn performs abortions through 13.9 weeks of pregnancy measured from the pregnant woman's lmp. On average, Dr. Lynn performs 407 first trimester abortions per year in his Beaufort office and 536 first trimester abortions per year in his Greenville office.

All of the abortions performed at GWC, CWMC, and Dr. Lynn's two practices are first trimester abortions. In fact, there are no abortion providers in South Carolina who perform elective abortions (those not associated with medical complications) in the second trimester of pregnancy.[4]

The most common first trimester abortion procedure performed by the plaintiffs is the suction curettage procedure. The suction curettage procedure is also utilized for spontaneous miscarriages. Although not wholly without risks, it is undisputed that a suction curettage abortion during the first trimester of pregnancy is a safe and quick medical procedure performed between six and fourteen weeks after a

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[4] Because the plaintiffs in this case only provide abortions during the first trimester of pregnancy, the plaintiffs' challenge to Regulation 61-12 is limited to its application to providers of first trimester abortions in South Carolina. Accordingly, I express no opinion as to the constitutionality of Regulation 61-12 as applied to facilities that may seek to perform second trimester abortions in the future.

woman's lmp.[5] It involves dilating the cervix, inserting a suction catheter into the uterus, and applying suction to remove the contents of the uterus. Although the patient is usually in the procedure room for a total of ten minutes, the procedure itself only takes approximately two to five minutes. It involves no incision and a minimum of bleeding. The procedure is also performed under general anesthesia or by applying a numbing medicine around the cervix. After the procedure, patients usually walk to the recovery area, where their pulse and blood pressure are monitored, and they are checked for any abnormal bleeding. Possible complications from the suction curettage procedure are fainting from vasovagal response, uterine perforation, excessive bleeding, infection, and retained tissue in the uterus. However, while the total complication rate for the procedure is about one in one hundred, serious complications are rare. The rate for complications requiring hospitalization is only about one in 2000. And the mortality rate is one in 100,000, which is about twenty-five times less risky than carrying a pregnancy to term. There is no evidence in this case that a first trimester suction curettage abortion has ever resulted in a woman's death in South Carolina.

Physicians in South Carolina, including Dr. Buffkin and Dr. Campbell, also perform medical abortions to terminate pregnancies located outside the uterus (such as in the fallopian tube) during the first six to seven weeks of pregnancy. A medical abortion is an even safer procedure than the suction curettage procedure. It involves the performance of a routine blood test to measure the patient's hormone levels, followed by the injection of a drug (methotrexate) into the patient's arm. There is no recovery

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[5] By way of comparison, according to one of the plaintiffs' experts whose testimony was credited by the district court, having a first trimester suction curettage abortion is safer than having a shot of penicillin in a physician's office.

time after the injection, and only mild vaginal bleeding. Follow-up care consists of rechecking the patient's hormone levels several days after the injection, and rechecks thereafter at seven-day intervals. Although currently limited in use to the termination of ectopic pregnancies, methotrexate and a second drug, RU-486, are currently being used in research protocols for use in terminating intrauterine pregnancies.

C

Currently, South Carolina does not require licensing of physicians' offices outside of the abortion context. Furthermore, physicians licensed to practice medicine in South Carolina are not subject to DHEC regulation, but rather are governed by the South Carolina State Board of Medical Examiners. *See* S.C. Code Ann. §§ 40-47-5 to 40-47-270 (West Supp. 1999). The State Board of Medical Examiners handles the examination and licensure of physicians within South Carolina, complaints against physicians, the suspension and revocation of licenses when appropriate, and the imposition of civil penalties and other sanctions against physicians. With the exception of standard building codes imposed by their particular locales, physicians' offices are not subject to any mandated design and construction requirements. Notably, unlike abortion clinics, physicians' offices that do not perform five or more abortions per month are not subject to the requirements of Regulation 61-12.

Regulation 61-12 is divided into ten "Parts." Part I of Regulation 61-12 sets forth "Definitions" and general "Requirements for Licensure" of abortion clinics. Part I defines an abortion as "[t]he use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to

remove a dead fetus." S.C. Code Ann. Regs. 61-12, § 101(A). Part I defines an abortion clinic as "[a]ny facility, other than a hospital ... in which any second trimester or five or more first trimester abortions per month are performed." *Id.* § 101(B).

In order to operate an abortion clinic, the clinic must first obtain a license from DHEC. *See id.* § 102(A). Prior to the issuance of a license, the abortion clinic must undergo a pre-licensure inspection. *See id.* § 102(F). Once the initial license is obtained, the abortion clinic must be inspected annually in order to obtain renewal of the license. *See id.* §§ 102(F), (H). In addition, Regulation 61-12 provides that the abortion clinic is subject to unannounced inspections by DHEC, *see id.* § 102(F)(1), during which DHEC inspectors "have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations." *Id.* § 102(F)(2).

Upon a determination by DHEC that an abortion clinic is in violation of "any statutory provision, rule or regulation relating to the operation or maintenance of such facility," DHEC may deny, suspend, or revoke the license. *Id.* § 103. In addition, DHEC may assess a monetary penalty up to $5,000 for each violation. *See id.* § 103(F). The amount of a penalty is based upon the specific provision at issue, which has been preassigned as either a Class I, II, or III violation, with a Class I violation being the most serious. *See id.*

Part II concerns the "Administration and Management" of the abortion clinic. Section 201 requires an abortion clinic to develop and implement detailed written policies and procedures for the operation of the clinic, which must include, at a minimum, policies and procedures to assure compliance with all federal, state, and local laws which govern the clinic; the designation of a person to whom

responsibility for operation and maintenance of the abortion clinic is delegated and the establishment of methods for holding the person responsible; personnel policies and procedures, including in-service training requirements; a facility-wide quality improvement program, including statistical summaries and a written plan of implementation; a policy and procedure for patient rights and grievance procedures; functional safety and maintenance policies and procedures; a policy and procedure for incident reporting; and policies and procedures for obtaining informed consent from the patient. *See id.* § 201(B). In addition, the abortion clinic's policies and procedures must include a provision for annual review and evaluation of the clinic's other policies and procedures, as well as for its management and operation. *See id.*

Section 203 requires an abortion clinic to maintain on file all current policies and procedures concerning the operation of the clinic, memoranda of agreements and credentialing documentation, a copy of Regulation 61-12, annual elevator safety inspections, and annual heating, ventilation, and air conditioning inspection reports. *See id.* §§ 203(A)-(E).

Section 204 sets forth detailed personnel requirements for each abortion clinic. The abortion clinic must obtain and verify professional and personal background information on every employee, *see id.* § 204(A), and must develop and implement a written orientation program for new staff members, to include orientation on the clinic's other policies and procedures, *see id.* § 204(E). A formal, in-service training program must also be planned and provided for all employees and volunteers, and records kept of attendance. *See id.* § 204(F). The in-service training of all employees and volunteers must include four specified areas -- infection control, fire protection, confidentiality and patient rights, and licensing regulations. *See id.* Written job descriptions must be prepared and reviewed annually, *see id.* § 204(G), and a

personnel file must be maintained on each employee and contain the employee's current job description that reflects the employee's responsibilities and work assignments, documentation of the employee's orientation, in-service education, appropriate licensure (if applicable) and tuberculin skin testing, *see id.* § 204(H). Annually, each employee must have a tuberculin skin test or, if previously positive, a chest x-ray to determine whether tuberculosis is present. *See id.* § 204(B). If tuberculosis is diagnosed, the abortion clinic must provide treatment and investigate employee contacts. *See id.* Employees and volunteers are also banned from working if they have any infected wounds, boils, sores, acute respiratory infections, or any other contagious disease or illness. *See id.* § 204(D). In addition, all professional and allied health care staff members must be certified by the American Red Cross or the American Heart Association as capable of performing CPR, although only one such certified person must be with patients when they undergo the abortion procedure and during the recovery period. *See id.* § 204(C).

Section 205 sets forth requirements for the clinical staff of an abortion clinic, which encompasses all physicians, nurses, and allied health professionals. *See id.* § 205(A). Abortions may only be performed by physicians licensed to practice medicine in South Carolina and who are also "properly qualified by training and experience to perform pregnancy termination procedures." *See id.* § 205(C). The abortion clinic must also obtain and maintain signed, written agreements with at least one physician board certified in obstetrics and gynecology who has admitting privileges at a local hospital which provides obstetrical and gynecological services. *See id.* All nursing care is required to be under the supervision of a registered nurse licensed in the State of South Carolina, regardless of the presence of a physician in the abortion clinic, and the registered nurse must be "on duty to provide or supervise all nursing care" during preparation, the procedure, recovery, and discharge. *Id.* § 205(D).

Licensed practical nurses may be employed so long as they work under the supervision and direction of a registered nurse. *See id.* § 205(E). Ultrasounds may only be conducted by physicians or ultrasound technicians who have documented evidence of completion of a training course in ultrasonography. *See id.* § 205(F). Finally, the entire clinical staff must participate in quarterly meetings to review and analyze clinical experiences, and minutes must be kept and maintained of each meeting. *See id.* § 205(B).

Section 209 requires an abortion clinic to "have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with [DHEC]." *Id.* § 209(A). A copy of the patient's rights must be conspicuously displayed, and a copy must be signed by each patient and included in the patient's medical record. *See id.* § 209(B).

Part III of Regulation 61-12 sets forth requirements for "Patient Care." Additional "patient care policies and procedures designed to ensure professional and safe care for patients" must be developed, *id.* § 301, and must include, but are not limited to, policies and procedures for admission criteria; physician and nurse responsibilities; details regarding the pre-operative procedures (including history and physical examinations, special examinations, lab procedures and consultations which will be required, and ultrasonography procedures); details regarding the actual abortion procedure (including the use of IVs, fluids, analgesia, anesthesia, and tissue examination and disposal); details regarding post-procedure care and recovery room care, including emergency care; provisions for education of the patient, family and others, as appropriate in pre- and post-procedure care; plans for follow-up care, including arrangements for a post-operative visit and specific instructions in the event of an emergency; procedures for the management and referral of high-risk conditions; procedures

for the transfer of patients when needed; procedures for infection control and sanitation (including duties and responsibilities of an infection control committee which are, in turn, charged with the responsibility of developing and implementing specific patient care and administrative policies to investigate, control, and prevent infections in the clinic); and procedures for the registration of fetal death or death certificates. *See id.* §§ 301(A)-(K).

Section 303 of Regulation 61-12 relates to an abortion clinic's pharmaceutical services. Section 303 requires every abortion clinic to maintain an emergency supply of drugs and medicines to treat, at a minimum, the following conditions: (1) cardiac arrest; (2) seizure; (3) asthmatic attack; (4) allergic reaction; (5) narcotic toxicity; (6) hypovolemic shock; and (7) vasovagal shock. *See id.* § 303(A). In addition, Section 303 mandates that the medicines must be prepared in an area that contains a sink and a counter. *See id.* § 303(D).

Section 304 requires laboratory services to be performed in compliance with the requirements already mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), 42 U.S.C. § 263a.[6] *See* S.C. Code Ann. Regs. 61-12, § 304(A). It further requires the physician to perform a urine pregnancy test (unless fetal heart beats or movements are identified on physical examination), a urinalysis which includes albumin and glucose examination, and a hematocrit or hemoglobin test. *See id.* § 304(B). In addition, the physician must perform a test to determine Rh factor. *See id.* If the patient is Rh positive, an additional Du variant test is required. *See id.* Rh(D) immune globulin must be administered if the patient is determined to be Rh negative. *See id.* Testing for chlamydia and gonorrhea is mandatory,

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[6] CLIA-88 has been amended, *see* 42 U.S.C.A. § 263a (West 1999). This amendment has no relevance to this case.

while testing for syphilis serology and performance of a Papanicolaou (pap) smear must be offered to the patient. *See id.* § 304(C).

Section 305 provides additional requirements for emergency care. It requires that "[a]ll staff and/or consulting physicians" have admitting privileges at one or more local hospitals that provide appropriate obstetrical/gynecological services or have in place documented arrangements approved by DHEC for the transfer of emergency cases when hospitalization becomes necessary. *Id.* § 305(A). The abortion clinic must maintain equipment and services to render emergency resuscitative and life-support procedures pending transfer. *See id.* § 305(B). And the abortion clinic must notify, in writing, the local ambulance service of the location of the clinic and the nature of the medical problems which may result from abortions. *See id.* § 305(C).

Section 306 requires an abortion clinic to purchase and maintain specific equipment and supplies, including such items as "[a] bed or recliner suitable for recovery," oxygen, mechanical suction, resuscitative equipment, emergency medications and intravenous fluids, "[a] clock with a sweep second hand," sterile suturing equipment and supplies, an adjustable examination light, and soiled linen and waste containers. *Id.* §§ 306(A)-(I).

Section 307 requires an abortion clinic to make "[a]rrangements ... for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed." *Id.* § 307.

Section 308, entitled "Quality Improvement," mandates a written plan for a quality improvement program for patient care and designation of an individual responsible for

coordinating the program. *See id.* § 308(A). Specific requirements include ongoing monitoring and evaluation of "patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services." *Id.* § 308(B). Evaluation of patient care is required to be "criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified." *Id.* § 308(C). The process must incorporate a quarterly review of a minimum of five percent of the medical records per quarter, but not less than five records per quarter shall be reviewed, *see id.* § 308(D), and must include a means of obtaining input from families of patients if they are "involved in the care and services provided by the facility." *Id.* § 308(E). The abortion clinic administrator must review the findings of the program and ensure corrective actions are taken. *See id.* § 308(F). The program must also identify and establish indicators of quality care, specific to the abortion clinic, that must be monitored and evaluated. *See id.* § 308(G). Annual review of the results is also required. *See id.* § 308(H).

Part IV of Regulation 61-12 sets forth requirements for "Medical Records and Reports." Section 401 begins by setting forth detailed requirements for the preparation and maintenance of medical records, which must include, at a minimum, twenty categories of information. *See id.* § 401. Section 401 requires a face sheet with patient identification data, including but not limited to, the patient's name, address, telephone number, social security number, date of birth, the father and mother's name if the patient is a minor, the husband's name, and the name, address, and telephone number of a person to be notified in the event of an emergency. *See id.* § 401(A)(1). The records are required to be kept confidential by the abortion clinic (although no such requirement is imposed upon DHEC inspectors who obtain

them) and must be stored for a minimum of ten years. *See id.* § 402.

Section 403 requires the preparation of additional reports, including a record of every accident or incident occurring in the abortion clinic which involves patients, staff, or visitors. *See id.* § 403(B). If it results in serious injury, the accident or incident must be self-reported to DHEC. *See id.* Serious injuries "include, but are not limited to," accidents and incidents that lead to hospitalization or death (other than of a fetus) and adverse drug reactions. *Id.*

Part V of Regulation 61-12, entitled "Functional Safety and Maintenance," requires additional policies and procedures, including, but not limited to, safety rules and practices for personnel, equipment, gases, liquids, drugs, supplies, and services; provisions for investigating accidents on the premises; provisions for disseminating safety-related information to employees and users of the abortion clinic; provisions for syringe and needle handling and storage; and provisions for managing infectious waste in accordance with another DHEC regulation already governing such matters. *See id.* §§ 501(A)-(B). In addition, the abortion clinic must prepare and post a disaster preparedness plan for evacuation in the event of a fire or other emergency. *See id.* § 502(A). All parts and portions of the abortion clinic are generically required to be kept "in good repair and operating condition," and "free of hazards." *Id.* § 503(A). In addition, "[a]ll wooden surfaces shall be sealed with a non-lead based paint, lacquer, varnish, or shellac that will allow sanitization." *Id.* A written preventive maintenance program must be developed and implemented for patient monitoring equipment and tested in accordance with manufacturer's specifications, but not less than annually. *See id.* § 503(B). Records of maintenance and testing must be kept. *See id.*

Part VI of Regulation 61-12 is entitled "Infection Control

and Sanitation." Part VI requires policies and procedures be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection. *See id.* § 601(A). Part VI also sets forth specific requirements for sterilization, including daily testing of the autoclave and a log of results, as well as periodic calibration and preventative maintenance as necessary, but not less than annually. *See id.* §§ 602(B)-(C). This part of Regulation 61-12 also requires that the abortion clinic "be kept neat, clean, and free from odors," *id.* § 604(A), mandates specific requirements for cleaning methods to be used and prohibits others, and imposes requirements for refuse and waste disposal, *see id.* §§ 604(A)-(C), 605. Section 606 requires that "[a]ll outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests," and that all "[o]utside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow, and other impediments." *Id.* § 606.

Part VII of Regulation 61-12, entitled "Fire Protection and Prevention," provides detailed requirements for firefighting equipment and systems, an evacuation plan, training of employees in the evacuation plan, mandatory fire drills at least once every three months, maintenance of fire equipment, and maintenance of records proving compliance with the provisions. *See id.* §§ 701-03.

Part VIII of Regulation 61-12 sets forth detailed requirements for the "Design and Construction" of abortion clinics. There is no grandfathering provision (unlike other DHEC regulations governing medical and patient care facilities) -- rather, all abortion clinics must be in full compliance within two years. *See id.* § 804. The requirements are set forth in detail, rendering a summary of them unproductive. Of note, Part VIII governs the number and size of procedure and recovery rooms, specifies the

design and equipment required in toilet rooms, regulates the direction of the air flow within the sterilization rooms, mandates a minimum width for doors and corridors, sets forth specific requirements for heating and air conditioning (the unit must be capable of maintaining a temperature between seventy-two and seventy-six degrees), regulates the abortion clinic's air supply and exhaust, regulates design criteria for abortion clinic entrances, sets forth specific requirements for the janitor's closets, and specifies the corridor glazing materials, wall finishes, wall bases, and interior finish materials that must be present. *See id.* §§ 807(A)-(Y).

Part IX of Regulation 61-12 sets forth additional "Prerequisites for Initial Licensure" of the abortion clinic, including plan and construction approval by DHEC, and specifies the documentation required to be submitted with the abortion clinic's initial application for licensure. *See id.* Part IX(A)-(B). Part X of Regulation 61-12, entitled "General," states in its entirety that "[c]onditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department." *Id.* Part X.

D

As noted earlier, prior to 1995, the State of South Carolina only required licensing of physicians' offices or other facilities in which second trimester abortions were performed. *See* S.C. Ann. §§ 44-41-20(b), -70(b) (Law. Co-op. 1995). Effective, January 3, 1995, Chapter 41 of Title 44 was amended as follows:

> (A) A facility in which any second trimester or five or more first trimester abortions are performed in a month must be licensed by [DHEC] to operate as an abortion clinic and must comply with the provisions

of Article 3 [the Woman's Right to Know Act].

(B) The department shall promulgate regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section.

Id. § 44-41-75 (West Supp. 1999). Pursuant to this enabling legislation, DHEC promulgated Regulation 61-12.

After the legislation requiring licensure of abortion clinics was passed, Alan Samuels (Samuels) of DHEC was charged with the responsibility for supervising the drafting and promulgation of Regulation 61-12. Although Samuels has some experience in health care administration, he has received no formal medical training or education. Upon completion of his college education, Samuels served in the United States Army for twenty-four years, where he served with the adjutant general corps and the medical services corps as a personnel officer and hospital inspector. After leaving military service, Samuels began employment with DHEC, where his duties consisted of inspecting various types of health care facilities for compliance with existing regulations. He was eventually promoted to the position of director of DHEC's Health Licensing Division, and now is retired.

Although Samuels provided some input and edits during the drafting process, he did not personally draft any portions of Regulation 61-12. Rather, he delegated the primary drafting responsibility to George Moore (Moore), who was the Director of Outpatient and Home Care within DHEC's

Division of Health Licensing. Samuels testified that, when Regulation 61-12 was promulgated, he knew very little about abortion procedures or the differences between first trimester and second trimester abortions. The record reflects that Samuels conducted no meaningful study or research into the differences between a first and second trimester abortion, and conducted no meaningful inquiry into what regulatory requirements were appropriate for facilities performing only first trimester abortions.

Like Samuels, Moore has some education and experience with hospital administration, but has received no formal medical training or education. After receiving an undergraduate degree, Moore joined the United States Army where he served twenty-five years. He spent the early part of his service in the adjutant general corps performing general administrative duties, after which time he transferred to the medical services corps where he performed administrative duties associated with health care facilities and hospitals. During his service, Moore received a master's degree in hospital administration. Upon his retirement from military service in 1988, Moore began employment with DHEC, inspecting hospitals and nursing homes for compliance with existing regulations. He was later promoted to Director of Outpatient and Home Care within the Division of Health Licensing, the position he held when Samuels asked him to assume primary responsibility for the drafting of Regulation 61-12.

In preparation for drafting Regulation 61-12, however, Moore took no meaningful steps to educate himself about first trimester abortions, how they differed from second trimester abortions, or what requirements would be appropriate for a facility which performed only first trimester abortions.

For assistance with Parts VII and VIII of Regulation 61-

12, Moore turned to William Lafferty (Lafferty), who was the Director of Health Facilities Construction with DHEC. Like Samuels and Moore, Lafferty has received no formal medical training or education. In drafting these portions of the regulations, Lafferty made no effort to determine whether the requirements were medically appropriate for facilities performing only first trimester abortions. Lafferty also approached the design and construction requirements from the standpoint of new construction requirements and anticipated that existing facilities would be grandfathered. The decision to include a mandatory two- year compliance provision in that portion of Regulation 61-12 instead of a grandfather provision was not made by Lafferty.

According to Moore, the preexisting South Carolina regulation governing second trimester abortions was utilized as a starting point for the new regulation, and many of the additional provisions of Regulation 61-12 were simply adopted or derived from DHEC regulations governing other types of health care facilities. They included regulations governing ambulatory surgical centers, renal dialysis facilities, community residential care facilities, day care facilities for adults, outpatient facilities for chemically dependent persons, habitation centers for the mentally retarded, residential treatment facilities for children and adolescents, nursing homes, and facilities providing home health care and hospice services. According to the DHEC officials, DHEC sought to standardize its regulations governing medical facilities and medical care so that the licensing requirements would have consistent wording, and to codify existing departmental practices. According to the DHEC officials, this attempt to standardize its regulations and to codify existing practices included DHEC's desire to grant its inspectors the authority to copy medical records in all medical facilities. According to Moore, departmental practice currently allows the copying of medical records during a complaint investigation. Moreover, Moore testified

that DHEC would maintain the confidentiality of the records even though there is no provision in Regulation 61-12 that mandates such confidentiality. [7]

Although the DHEC officials testified that they primarily utilized existing South Carolina regulations as the basis for drafting Regulation 61-12, there is evidence in the record that the DHEC officials consulted other points of reference. First, Moore obtained copies of abortion regulations from North Carolina and Tennessee, though he did not speak with anyone in those states about the regulations or how they had affected maternal health. Second, Moore reviewed standards and guidelines issued by the Planned Parenthood Federation of America, Inc. (Planned Parenthood), the National Abortion Federation (NAF), and the American College of Obstetricians and Gynecologists (ACOG). The standards and guidelines published by Planned Parenthood, NAF, and ACOG are not mandated standards of care which can or should be imposed on licensed physicians. Rather, they are guidelines which should be followed with due regard for the medical judgment of the treating physician and the special needs of the patients that they serve.

During the drafting process, the general counsel of ACOG wrote a letter to DHEC expressing concern that the requirements of Regulation 61-12 would not enhance patient well-being or safety and offering DHEC the assistance of ACOG in the drafting of an appropriate regulation. The DHEC drafters declined ACOG's assistance.

After an initial draft of Regulation 61-12 was completed,

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[7] Interestingly, DHEC's regulation governing ambulatory surgical centers contains a specific provision protecting the confidentiality of medical records. *See* S.C. Code Ann. Regs. 61-91, § 1001(E) (providing that records may only be removed from the premises by subpoena or court order).

Moore requested limited input and comments from two medical personnel associated with DHEC. The first, Dr. Richard Goodrich (Dr. Goodrich), is a licensed physician, board certified in obstetrics and gynecology, who practiced in Zanesville, Ohio until he retired. After his retirement, he moved to South Carolina and became a consultant with DHEC in the area of maternal and child health. During his medical practice, however, Dr. Goodrich performed only two abortions, both of which were due to medical complications. Furthermore, Dr. Goodrich was not asked to and did not draft any portion of Regulation 61-12. Rather, he was only asked to review discrete portions of the regulation dealing exclusively with medical events and medical testing, and he conducted no review of and provided no input on the majority of the regulatory requirements. Although he is of the opinion that the portions of Regulation 61-12 that he reviewed are appropriate medical standards of care, he testified that the same standards would be appropriate for physicians' offices in which comparable obstetrical and gynecological surgical procedures are performed. Dr. Goodrich further testified that he did not recommend Regulation 61-12's requirement of physician qualifications beyond state licensure, and acknowledged that he did not know how the required "training and experience" qualifications could be determined under the regulation. Dr. Goodrich also interpreted Regulation 61-12's requirement that a registered nurse be "on duty" as requiring that a registered nurse have ultimate responsibility, and not that a registered nurse should or needs to be on the premises at all times. Dr. Goodrich further testified that, while he has no specific experience with medical abortions, it would not be his intent to cover the provision of medical abortions under the regulation. He acknowledged, however, that the regulation as drafted would in fact cover such abortions. Finally, Dr. Goodrich testified that he is aware of no existing problem with abortion providers in South Carolina and has no opinion as to how the cost and availability of abortions

affect women's health issues.

Moore also sought some limited input from Robert Lawyer, R.N. (Lawyer), who was Director of Nursing for DHEC. Lawyer received his bachelor of science degree in nursing while in the United States Army, and later received a masters degree in health services management and business administration. He has some experience with providing nursing care for first and second trimester abortions performed in a military hospital. After retiring from the Army in 1989, Lawyer began working with DHEC. He is currently nurse manager with the Division of Health Licensing, where his primary duty is the inspection of various health care facilities for compliance with existing regulations. He too was asked by Moore and Samuels to review and provide input concerning discrete portions of Regulation 61-12, primarily those governing nursing care. Lawyer is of the opinion that, for first trimester abortions, a registered nurse should either personally monitor the patient or supervise all patient care, unless the physician is present in the abortion clinic and available to come to the recovery room if necessary. Unlike Dr. Goodrich, however, he interprets Regulation 61-12 as requiring the "on duty" registered nurse to be on the premises. In formulating his opinion, Lawyer did not conduct any research on abortion practices in South Carolina, nor did he consult with nursing professionals who specialize in abortion procedures. Lawyer testified that while he is aware that Regulation 61-12 would apply to facilities performing only medical abortions, he has no knowledge of what nursing skills are required in the context of medical abortions or whether they would require a registered nurse as opposed to a licensed practical nurse.

With the exception of these limited consultations with medical personnel associated with DHEC, the drafters of Regulation 61-12 did not seek any input from medical professionals during the drafting process and rejected

ACOG's offer of assistance. As some support for the text of Regulation 61-12, the defendants contend that the drafters conducted an inspection of Planned Parenthood's abortion clinic in Columbia, South Carolina and determined that the clinic met the great majority of Regulation 61-12's requirements. The evidence credited by the district court, however, reveals that the drafters simply toured the clinic and, during one such visit, may have spoken briefly to a Planned Parenthood physician. There is no evidence that the physician was asked to comment upon the regulatory requirements or whether they were medically necessary for first trimester abortions. Moreover, there is no evidence in the record to support a finding that DHEC received any meaningful input from Planned Parenthood physicians prior to or during the early stages of the drafting process.

After the initial drafting process was concluded, DHEC issued a proposed regulation and held public hearings as mandated by South Carolina law. Some of the suggestions made during this public comment period resulted in changes to Regulation 61-12, including some suggestions made by Planned Parenthood and the plaintiffs in this case.

On January 23, 1996, DHEC submitted Regulation 61-12 to the South Carolina legislature for approval as required by South Carolina law. Because the legislature took no action on Regulation 61-12 within 120 days after its submission, it became effective automatically upon publication in the State Register on June 28, 1996.

E

Based on the evidence presented at trial, the district court made detailed findings concerning Regulation 61-12 and its probable effect on the health of women in South Carolina, the cost of obtaining a first trimester abortion in South Carolina, and the availability for obtaining a first trimester

abortion in South Carolina. First, based on the evidence in the record, the district court found that the first trimester suction curettage abortion is one of the safest surgical procedures that can be performed. The procedure lasts approximately two to five minutes and has a low overall complication rate. Suction curettage abortions can be, and are currently being, safely performed in physicians' offices and outpatient clinics, except where the patient has particular medical conditions that would require the procedure to be performed in an ambulatory surgical center or hospital. Medical abortions are also quick medical procedures that can be safely performed in a physician's office or outpatient clinic. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 718.

Second, the district court found that physicians' offices and clinics that provide less than five first trimester abortions per month perform identical procedures to those which provide five or more first trimester abortions per month, and the risk to the patient undergoing the abortion procedure is identical. *See id.*

Third, the district court found that first trimester suction curettage abortions are comparable in terms of risks, duration, and invasiveness to a variety of obstetrical and gynecological surgical procedures which are frequently performed in physicians' offices in South Carolina. These would include suction curettage procedures performed on women who have experienced an incomplete spontaneous abortion, dilation and curettage procedures, endometrial biopsies, hysteroscopies, and insertion of intrauterine devices for birth control. *See id.*

Fourth, the district court found that first trimester suction curettage abortions are also comparable in terms of risks, duration, and invasiveness to a variety of non-obstetrical/gynecological surgical procedures that are

frequently performed in physicians' offices in South Carolina. These would include the removal of subcutaneous lipomas and cysts, minor breast biopsies, and the removal of implanted ports and catheters which have been inserted into large veins in the neck and collarbone region for use in administering chemotherapy and dialysis. *See id.*

Fifth, the district court found that South Carolina is not currently experiencing a public health problem related to the provision of first trimester abortions by licensed physicians, nor was the state experiencing such a problem when Regulation 61-12 was promulgated. The district court found no evidence that the plaintiffs or any other abortion providers in South Carolina are providing inadequate care to women seeking abortions or that the rate of complications from abortions performed in South Carolina is greater than the national average. On the contrary, the district court found that South Carolina has experienced a similar, if not lower, average complication rate. *See id.* at 718-19.

Sixth, the district court found that, although the principal draftsmen of Regulation 61-12 have some expertise in hospital and health care administration, they have no training or education in the provision of hands-on medical care and little knowledge of the medical needs of women seeking first trimester abortions in South Carolina. *See id.* at 719. The district court found that they engaged in virtually no research, investigation, or other efforts to determine what types of requirements would be necessary or advisable for the abortion procedure, or what types of requirements would further or hinder the state's interest in maternal health. Nor did DHEC officials possess or seek information concerning the present safety of first trimester abortions or the relative risks associated with the procedure. *See id.*

Seventh, the district court found that, despite their admitted lack of medical knowledge in general and of

abortion procedures in particular, the drafters of Regulation 61-12 sought only minimal input and assistance from knowledgeable medical experts during the drafting process, choosing to rely solely upon the limited review and advice of Dr. Goodrich and Lawyer as to discrete portions of the regulation. *See id.* Furthermore, DHEC either rejected or ignored an offer by ACOG to assist in the drafting process. Although DHEC was under no legal obligation to consult with ACOG or to accept their assistance during the drafting process, the district court found that ACOG is unanimously considered to be a well-respected medical organization dedicated to improving the standard of health care in the field of obstetrics and gynecology. *See id.* According to the district court, DHEC's rejection of ACOG's assistance further demonstrated DHEC's lack of interest in ensuring that Regulation 61-12 actually met the proffered goal of promoting maternal health and is consistent with the testimony of the DHEC witnesses that such a goal was not their primary motivation during the drafting process. *See id.*

Eighth, the district court found that, although it is uncontroverted that first trimester abortions are significantly less risky to the health of women than second trimester abortions, an existing South Carolina regulation governing second trimester abortions was utilized as a starting point for Regulation 61-12. With the exception of Section 309 of Regulation 61-12 which specifically pertains to second trimester abortions,[8] the DHEC drafters drew no distinction between first and second trimester abortions in the text of the regulation. In addition, the DHEC drafters admitted that virtually no such distinctions were considered during the drafting process. *See id.*

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[8] Section 309 mandates additional qualifications which the performing physician must possess, additional equipment which must be on hand, and additional medical tests which must be administered for second trimester abortions. *See* S.C. Code Ann. Regs. 61-12, §§ 309(A)-(D).

Ninth, the district court found that, instead of attempting to tailor Regulation 61-12 to the particularized medical needs of women seeking first trimester abortion services in South Carolina, DHEC's goal during the drafting process was to standardize its health care and facility regulations and to codify existing departmental practices. *See id.* at 719-20. According to the district court, to the extent this was done, it was done without any meaningful inquiry or assessment as to whether the requirements would further the state's interest in maternal health and without assessing whether first trimester abortions were comparable to the procedures performed in the other facilities regulated by DHEC. *See id.* at 720. The district court further found that clinics that provide first trimester abortions provide services that are significantly less risky, invasive, and lengthy than the services offered in ambulatory surgical centers, yet many of the requirements of Regulation 61-12 are as stringent, or in some respects more stringent, than those imposed upon ambulatory surgical centers.[9] *See id.*

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[9] In fact, Regulation 61-12 recognizes that the risks and potential complications of surgical procedures typically performed in ambulatory surgical centers are significantly higher than those associated with first trimester abortions. Under Regulation 61-12, licensed abortion clinics are restricted to performing abortions through eighteen weeks of pregnancy measured from the pregnant woman's lmp. *See* S.C. Code Ann. Regs. 61-12, § 302(A). Abortion clinics performing abortions beyond fourteen weeks of pregnancy measured from the pregnant woman's lmp must meet the additional patient requirements in Section 309 of Regulation 61-12, which requires additional physician qualifications, medical equipment, and mandatory laboratory tests. *See id.* § 302(B). Abortions beyond eighteen weeks of pregnancy measured from the pregnant woman's lmp must be performed in a hospital, although a licensed ambulatory surgical center that is also licensed as an abortion clinic may perform abortions on patients through twenty-six weeks of pregnancy measured from the pregnant woman's lmp. *See id.* § 302(A).

Tenth, the district court found that Planned Parenthood, NAF, and ACOG standards and guidelines relied upon in part by DHEC are recommendations by the respective organizations and are not fairly characterized as mandated standards of care which can or should be imposed upon licensed physicians as regulatory requirements. Rather, they are guidelines which should be followed with due regard for the medical judgment of the treating physicians and the special needs of the patients they serve. Even if some of the existing guidelines could, in isolation, be appropriate matters for regulation, the district court found that Regulation 61-12 imposes requirements which greatly exceed the guidelines. *See id.*

Eleventh, the district court found that, in imposing the detailed requirements of Regulation 61-12, the DHEC drafters also failed to take any meaningful steps to evaluate the costs of compliance or its impact upon the availability of abortion services in South Carolina. *See id.* Based upon the evidence presented, the district court found that Regulation 61-12 will significantly increase the cost of abortion services in South Carolina. *See id.* The district court found that this increase in the cost of abortion services will delay a significant number of women from obtaining the procedure and, in some cases, result in their inability to obtain the procedure. *See id.* The district court further found that, as a pregnancy advances, the medical risks associated with abortion increase, and a full term pregnancy and childbirth is much more risky to the physical health of a woman than a first trimester abortion. *See id.*

Twelfth, the district court found that Regulation 61-12 contained a myriad of detailed and costly provisions that were medically unnecessary and, thus, were neither designed to further the health of women seeking first trimester abortions nor likely to accomplish this goal. For example, with respect to Part I of Regulation 61-12, the district court

observed that its definition of an "abortion" included medical abortions currently used to terminate ectopic pregnancies. *See id.* at 721. However, all of the evidence in the record, including the testimony of Dr. Goodrich, suggested that Regulation 61-12's stringent requirements were medically unnecessary for a physician or abortion clinic that performed only medical abortions.

With respect to Part II, the district court found that this portion of Regulation 61-12 is permeated with unnecessary requirements governing physician qualifications, staffing, and staff training. *See id.* The district court observed that Regulation 61-12 requires physicians and clinics to hire a registered nurse to supervise all nursing care in the abortion clinic regardless of the fact that a licensed physician is present in the clinic to supervise all medical care, including nursing care. *See id.* The district court found that it is within accepted medical practice, both within the abortion context and in physicians' offices performing comparable surgical procedures, for a physician to hire licensed practical nurses (who command a lower salary than registered nurses) so long as they act under the supervision of the attending physician. *See id.* The district court found that the defendants offered no persuasive reason why a physician could not supervise the nursing care of patients during the recovery process simply because the physician may be in another room for a brief period of time. *See id.* In making this finding, the district court recognized that even DHEC's own medical consultant, Dr. Goodrich, opined that a registered nurse need not be on the premises to supervise care -- only that the nurse have overall supervisory duties. *See id.*

Also with respect to Part II, the district court found that Part II's requirement that all abortion clinic health care personnel receive tuberculin skin testing is medically unnecessary in view of the fact that DHEC has not required such testing of all health care personnel and did not offer any

justification for arbitrarily requiring this testing of all abortion care workers, but not all other health care workers. *See id.* at 722.

The district court also found that Regulation 61-12's requirement that *all* allied health care personnel in abortion clinics receive CPR training, as opposed to having one qualified person at the clinic at all times, was medically unnecessary in view of the fact that this requirement is imposed solely upon abortion providers who perform, according to all of the witnesses, one of the safest surgical procedures that is performed in this country, and DHEC did not offer any justification for arbitrarily imposing this requirement. *See id.*

With respect to Part III, the district court found that the level of policies and procedures required by this part, as well as the extensive in- service training requirements and other policies required in Part II, are costly endeavors unsubstantiated by a medical need. *See id.* The district court observed that such requirements may be appropriate for large medical care facilities with large staffs that do not interact on a daily basis. *See id.* However, according to the district court, Regulation 61-12 arbitrarily imposes it upon every clinic and every physician's office which performs five or more first trimester abortions per month -- regardless of the number of staff or hours of operation. *See id.*

The district court also found that it was medically unnecessary to have every woman undergo (and pay for) testing for certain sexually transmitted diseases (but not others), without regard to whether such tests are medically indicated and indeed even when the physician determines that they are not, simply because the woman has chosen to obtain a first trimester abortion from a physician who

performs them on a regular basis.[10] *See id.* The district court further found that Section 307's requirement that abortion providers have "consulting" arrangements with various specialists before they can obtain a license to operate is medically unnecessary and unduly burdensome because no evidence was presented relating to why licensed physicians are not capable of exercising appropriate discretion in recognizing and acting upon the medical needs of their patients in this regard. *See id.* at 722-23.

Also with respect to Part III, the district court found that Regulation 61-12 inexplicably imposes requirements concerning access to emergency drugs which are not imposed upon any other physicians. *See id.* at 723. The district court also found that the equipment and supplies required by Regulation 61-12 will also increase the costs of providing abortions in South Carolina, and require equipment unnecessary for the safe performance of the first trimester abortion procedure. *See id.*

With respect to Part IV, the district court found that this part of Regulation 61-12 was particularly troubling. For example, the district court found that the requirement that a woman seeking an abortion provide the name of her spouse in addition to an emergency contact is a medically unnecessary requirement which imposes a substantial obstacle in the path of a woman who, for personal reasons, may not wish to disclose this information. *See id.* The district court also found that, although the abortion clinic was required to keep patient records confidential, nothing prohibited DHEC from publicizing these records once it

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[10] Of note, the district court found that the defendants presented insufficient evidence to support a finding that sexually transmitted diseases are more prevalent in woman seeking abortions or that abortion clinics present a public health problem in this regard. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 733 n.16.

obtained them pursuant to an inspection. *See id.* at 702.

With respect to Part VIII, the district court observed that this part of Regulation 61-12 imposed extensive and detailed design and construction requirements for abortion facilities, which far exceed building code requirements applicable to other physicians' offices, including those that perform identical and comparable procedures. *See id.* at 723. The district court found that these extensive requirements, while perhaps appropriate for a hospital or large ambulatory surgical center, are not justified by expected medical benefits to the women undergoing the relatively safe, first trimester suction curettage abortion in a small physician's office or clinic. *See id.*

Also with respect to Part VIII, the district court found that additional requirements, which were advanced as unique to the medical field, had no justification in medical necessity. For example, the district court found no evidence supporting a need for an abortion clinic to install additional bathroom equipment and emergency call buttons or that it have a recovery area separate from the procedure area. *See id.* at 724. The district court further found that no credible evidence was presented demonstrating that physicians should be required to widen their doors and corridors to a width sufficient to accommodate both an ambulance stretcher and a person walking alongside to perform cardiopulmonary resuscitation, particularly given the unanimous testimony that a first trimester abortion is a relatively safe procedure with infrequent complications. *See id.* The district court found no evidence that this need had ever arisen from the performance of a first trimester abortion in South Carolina or elsewhere. *See id.* Finally, the district court observed that physicians performing surgical procedures of comparable invasiveness and risk are not required to renovate their offices to meet a similar requirement. *See id.*

With respect to Part IX, the district court found that this part of Regulation 61-12 required numerous certifications and laboratory test results concerning various parts of the abortion clinic (such as the carpets and draperies) without any evidence that the these requirements would further the goal of protecting women's health in South Carolina. *See id.*

With respect to Part X, the district court observed that, in conjunction with Section 103(C), Part X grants to DHEC unfettered power to "manage [ ]" abortion providers "in accordance with the best practices as interpreted by the Department," S.C. Code Ann. Regs. 61-12, Part X, and to cite providers with a Class III violation and penalty if DHEC observes a condition deemed to be "against the best practices as interpreted by the Department," *id.* § 103(C). The district court found that Part X imposed upon abortion providers the additional burden of determining and complying with standards or practices not specified in the regulation, but which DHEC may in the future find to be "best" for an abortion clinic. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 724.

Finally, the district court found that a first trimester suction curettage abortion in South Carolina currently costs between $325 and $480, depending on the gestational age, the type of sedation or anesthesia needed, and the medical testing indicated. *See id.* at 717. The district court further found that Regulation 61-12 would raise the cost of each abortion performed by the plaintiffs in the following ranges:[11]

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[11] The lowest figure represents the defendants' revision of the plaintiffs' estimates of complying with Regulation 61-12. The highest figure represents the plaintiffs' estimate. The district court observed that neither figure, however, takes into account the standard 15% profit factor which the plaintiffs' accountant testified would be appropriate. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 717 n.10

(1) For CWMC, the cost will increase between $36.48 and $75.03;

(2) For Dr. Lynn's Greenville practice, the cost will increase between $93.09 and $170.39;

(3) For Dr. Lynn's Beaufort practice, the cost will increase between $115.67 and $367.50;

(4) For GWC, the cost will increase between $22.68 and $32.39.[12]

See id. The district court found that the substantial alterations that Dr. Lynn would have to undertake to bring his Beaufort practice in compliance with Regulation 61-12 will likely force him to close his practice, thereby eliminating the availability of abortions in this area of South Carolina.[13]

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[12] At trial, the parties entered into several notable stipulations concerning the cost of complying with certain specific provisions of Regulation 61-12:

(1) When directly billing physicians, laboratories in South Carolina generally charge between $20 and $40 per sample to perform a combined test for chlamydia and gonorrhea.

(2) When directly billing physicians, laboratories in South Carolina generally charge between $17 and $30 per sample to test for the Du variant.

(3) When directly billing physicians, laboratories in South Carolina charge between $7 and $20 per sample to perform a test for syphilis and between $10 and $22 to perform a test from a pap smear.

[13] At trial, the plaintiffs presented evidence that, to comply with Regulation 61-12, CWMC would require renovations costing approximately $27,235, that Dr. Lynn's Greenville practice would require renovations costing approximately $2,700, that Dr. Lynn's Beaufort office would need renovations costing approximately $12,256, and that GWC would need renovations costing approximately $3,700.

See id. The district court also found that the increased cost of providing abortions and/or the closure of the only abortion clinic in one area of a state resulting from Regulation 61-12 will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining the abortion, both of which carry increased risks to the health of women.[14] *See id.* at 718. The district court found that, as a pregnancy advances, the medical risks associated with an abortion procedure increase, and a full term pregnancy is more risky to the physical health of a woman than a first trimester abortion. *See id.* at 720.

F

Based on the findings of the district court summarized above, the district court concluded that Regulation 61-12 violated the Due Process and Equal Protection Clauses of the Fourteenth Amendment. *See id.* at 724-43. With respect to the Due Process Clause, the district court held that

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[14] The district court's finding in this regard was premised on the testimony of the plaintiffs' expert, Dr. Stanley Henshaw, who is currently deputy director of research at the Alan Guttmacher Institute in New York, where he conducts studies relating to family planning and abortion services. Dr. Henshaw testified that an increase in the price of abortion procedures prevents a number of women from obtaining abortions and causes other women to delay their abortions until further along into their pregnancies. Dr. Henshaw also testified that relatively small increases in the cost of an abortion will have this effect, and that an increase of just $25 can be expected to prevent one or two out of every 100 low-income women seeking an abortion from being able to obtain one. Dr. Henshaw also testified that a decrease in the number of abortion providers in South Carolina will result in a decrease in the number of women who are able to obtain an abortion in the state, and a corresponding increase in the number of women who must travel to obtain the procedure, *e.g.*, from Beaufort to Savannah, Georgia and/or Charleston, South Carolina. Such a need to travel will, in turn, reduce the ability to obtain an abortion or result in a delay in obtaining the abortion. And the need to travel carries its own costs, which will increase the overall cost of obtaining the abortion and compound the financial problem.

Regulation 61-12 failed to pass constitutional muster under either the facial invalidity standard set forth *in United States v. Salerno*, 481 U.S. 739 (1987), or the undue burden test set forth in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992) (plurality joint opinion of O'Connor, Kennedy, and Souter, J.J.). *See Greenville Women's Clinic*, 66 F. Supp. 2d at 727-37. With respect to the undue burden standard set forth in *Casey*, the district court held that Regulation 61-12 did not serve and was not designed to serve the state's interest in maternal health. *See id.* at 730-35. To the contrary, the district court concluded that Regulation 61-12 would likely harm the health of women in South Carolina. *See id.* Accordingly, the district court concluded that Regulation 61-12 was unconstitutional under *Casey*. *See id.* at 735. The district court also concluded that even if Regulation 61-12 furthered the state's interest in maternal health, the burdens imposed by Regulation 61-12 upon abortion patients and providers constituted an undue burden on a woman's right to have an abortion prior to viability. *See id.* at 735-43. With respect to the standard set forth in *Salerno*, the district court concluded that Regulation 61-12 was unconstitutional in all of its applications and, therefore, could not stand under *Salerno*. *See id.* at 736-43.

With respect to the Equal Protection Clause, the district court held that Regulation 61-12 violated the Equal Protection Clause under both the strict scrutiny test and the more lenient rational basis test. *See id.* at 737-43. With respect to the rational basis test, the district court held that Regulation 61-12 failed that test because it singles out physicians and abortion clinics performing five or more first trimester abortions per month from other physicians and clinics performing four or less first trimester abortions per month and/or other virtually identical procedures and places additional and onerous burdens upon physicians and abortion clinics which are neither justified by actual differences nor rationally related to the state's legitimate interest in

protecting the health and safety of women seeking first trimester abortions. *See id.* at 740-43.

Finally, the district court concluded, in light of both South Carolina law and the text of Regulation 61-12, that Regulation 61-12 was not subject to the doctrine of severability.[15] *See id.* at 743-44.

II

A

The Due Process Clause of the Fourteenth Amendment states that: "nor shall any State deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. "Although a literal reading of the Clause might suggest that it governs only the procedures by which a State may deprive persons of liberty, ... the Clause has been understood to contain a substantive component as well, one barring certain government actions regardless of the fairness of the procedures used to implement them." *Casey*, 505 U.S. at 846, (plurality joint opinion of O'Connor, Kennedy, and Souter, J.J.) (citation and internal quotation marks omitted). A woman's right to have an abortion is recognized as a fundamental right protected by the substantive component of the Due Process Clause of the Fourteenth Amendment. *See Roe v. Wade*, 410 U.S. 113, 155-66 (1973); *see also Manning v. Hunt*, 119 F.3d 254, 259 (4th Cir. 1997).[16]

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[15] In light of its ruling that Regulation 61-12 violated the Due Process and Equal Protection Clauses of the Fourteenth Amendment, the district court declined to address the plaintiffs' remaining claims that Regulation 61-12: (1) was unconstitutionally vague; (2) violated the abortion patients' confidentiality rights; and (3) violated the Establishment Clause of the First Amendment.

[16] Because Regulation 61-12 applies to first trimester abortion providers, the plaintiffs have standing to challenge the constitutionality of

In *Roe*, the Supreme Court overturned a Texas statute prohibiting abortions unless an abortion was necessary to save the life of the mother. *See* 410 U.S. at 117. The *Roe* Court held that the right of personal privacy includes the right to have an abortion, but that the right "is not unqualified and must be considered against important state interests in regulation." *Id.* at 154. The Court determined that because abortion is a fundamental right, state abortion regulations should be analyzed under the strict scrutiny standard of review, and are, therefore, valid only if the regulation can be justified by a compelling state interest and if the regulation was narrowly drawn to further only that legitimate state interest. *See id.* at 155. According to the Court, the state's interest in preserving and protecting the health of the mother and in protecting potential human life increase in substantiality as the woman approaches term, becoming compelling at some point in the pregnancy. *See id.* at 162-63.

The *Roe* Court found that during the first trimester of pregnancy the decision to abort must be left to the wishes of the mother and the judgment of the mother's physician; that during the time after the first trimester but before viability of the fetus, the state could regulate the abortion decision in ways reasonably related to maternal health; and that after viability, the state could regulate or proscribe abortion except when necessary to preserve the life or health of the mother. *See id.* at 164-65.

Since *Roe*, the Court has struggled to formulate a precise standard for reviewing facial challenges to abortion regulations. In *Salerno*, the Court explained that

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the regulation. *See Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 392 (1988); *Doe v. Bolton*, 410 U.S. 179, 188 (1973).

> [a] facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid. The fact that [an Act] might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid, since we have not recognized an "overbreadth" doctrine outside the limited context of the First Amendment.

481 U.S. at 745. Thus, under *Salerno*, a facial challenge to a statute will fail if the statute has any constitutional application. Following *Salerno*, the Supreme Court applied *Salerno*'s "no set of circumstances" test in a few pre-*Casey* cases involving abortion statutes. *See, e.g., Rust v. Sullivan*, 500 U.S. 173, 183 (1991).

In *Casey*, however, the Court held that an abortion law is unconstitutional on its face if, "in a large fraction of the cases in which [the statute] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." 505 U.S. at 895. Although *Casey* did not expressly overrule *Salerno*, it is inconsistent with *Salerno*. Under *Salerno*, no factual showing of unconstitutional application can render a law unconstitutional if it has any constitutional application. Under *Casey*, a factual showing of unconstitutional application in "a large fraction of the cases" where the law applies can render a law unconstitutional, even if it has some constitutional application.

In *Casey*'s wake, many circuit courts held that *Casey* displaced *Salerno* in the abortion context. *See, e.g., Planned Parenthood v. Lawall*, 180 F.3d 1022, 1027 (9th Cir.) ("In light of our previous suggestion, combined with the great weight of authority holding that *Casey* has overruled *Salerno* in the context of facial challenges to abortion statutes, we

apply *Casey*'s undue burden standard in determining the facial constitutionality of [the statute at issue]."), *amended by* 193 F.3d 1042 (9th Cir. 1999); *Women's Med. Prof'l Corp. v. Voinovich*, 130 F.3d 187, 193-96 (6th Cir. 1997) (concluding that *Salerno* is inapplicable to facial challenges to abortion regulations and applying *Casey*'s undue burden standard), *cert. denied*, 523 U.S. 1036 (1998); *Jane L. v. Bangerter*, 102 F.3d 1112, 1116 (10th Cir. 1996) (noting the difference between *Casey* and *Salerno* and applying *Casey*'s undue burden standard to facial abortion challenge); *Planned Parenthood v. Miller*, 63 F.3d 1452, 1458 (8th Cir. 1995) (choosing to follow "what the Supreme Court actually did -- rather than what it failed to say -- and apply the undue-burden test" to facial abortion challenge); *Casey v. Planned Parenthood*, 14 F.3d 848, 863 n.21 (3d Cir. 1994) (noting that Supreme Court in *Casey* "set a new standard for facial challenges to previability abortion laws"). The Fifth Circuit has applied the *Salerno* test to a facial abortion challenge after *Casey*, *see Barnes v. Moore*, 970 F.2d 12, 14 (5th Cir. 1992), but its application of *Salerno* has not been consistent, *see Sojourner T. v. Edwards*, 974 F.2d 27, 29-31 (5th Cir. 1992) (striking down statute banning abortions as clearly unconstitutional under *Casey*, even though it permitted abortions to save the life of the mother and, therefore, arguably passed constitutional muster under *Salerno*), and the Fifth Circuit has yet to resolve the inconsistency. *See Okpalobi v. Foster*, 190 F.3d 337, 354 (5th Cir. 1999) (noting inconsistency but declining to address it because challenged law failed under both *Casey* and *Salerno*).

However, our circuit never resolved the *Salerno/Casey* question, despite what the majority might have one believe. *See ante* at 12-13. In *Manning*, we applied the *Salerno* standard of review to an abortion statute, but the plaintiffs did not challenge its applicability. *See* 119 F.3d at 268 n.4. In *dicta*, however, the court suggested that we would nonetheless apply the *Salerno* standard until the Supreme

Court explicitly overruled it, stating that

> [i]t is not the province of the court of appeals to predict how the Supreme Court will ultimately rule on an issue. *Casey* does not specifically overrule *Salerno*. At the moment, the most that can be said is that three Justices have indicated a desire to do so. Until the Supreme Court specifically does so, though, this Court is bound to apply the *Salerno* standard as it has been repeatedly applied in the context of other abortion regulations reviewed by the Supreme Court.

Id.; *see also Planned Parenthood v. Camblos*, 155 F.3d 352, 381 n.14 (4th Cir. 1998) (*en banc*) (noting the *Manning dicta* but not deciding the question), *cert. denied*, 525 U.S. 1140 (1999); *id.* at 389 n.2 (Michael, J., concurring in the judgment) (asserting that *Casey*'s undue burden test must be applied to facial challenges to abortion restrictions).

The *Salerno/Casey* question was finally resolved by the Supreme Court in *Stenberg v. Carhart*, No. 99-830, 2000 WL 8258899 (U.S. June 28, 2000). In that case, a Nebraska physician brought a facial challenge to Nebraska's "partial birth" abortion statute. As interpreted by the Supreme Court, the Nebraska statute banned the performance of second trimester dilation and extraction (D&X) abortions, commonly referred to as "partial birth abortions," and the performance of dilation and evacuation (D&E) abortions, the most commonly used method for performing previability second trimester abortions. The Supreme Court applied *Casey* and concluded that the Nebraska statute was unconstitutional for two independent reasons. First, the Court concluded that the Nebraska statute was unconstitutional because the statute lacked any exception for the preservation of the health of the mother and the record evidence disclosed that, in some circumstances, a D&X abortion would be the safest abortion. *See Stenberg*, No. 99-830, 2000 WL 825889, at *10-14.

Second, the Court concluded that, because the Nebraska law applied to the performance of D&E abortions, the most commonly used method for performing previability second trimester abortions, the resulting fear of prosecution, conviction, and imprisonment felt by physicians who perform D&E abortions amounted to an undue burden on a woman's right to have an abortion. *See id.* at *15-19.

In this case, the district court did not resolve the *Salerno/Casey* question. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 726-27. Instead, the district court analyzed Regulation 61-12 under both standards and held that Regulation 61-12 failed to pass constitutional muster under either the *Salerno* or *Casey* standard. *See id.* at 727-37. Here, being bound by *Stenberg*, I only need to evaluate Regulation 61-12 under the principles set forth in *Casey*, as contrary to the majority's intimation, *see ante* at 12-13, *Salerno*, in the abortion context, is not recognized as the law by the current Supreme Court.

In *Casey*, the Supreme Court established the undue burden test for determining whether a statute restricting abortions could pass constitutional muster. Under *Casey*, a statute is invalid on its face if it places an undue burden on a woman's right to have an abortion before the fetus attains viability. *See* 505 U.S. at 878. An undue burden exists if the state regulation has the effect of placing a substantial obstacle in the path of a woman's choice to obtain an abortion before the fetus attains viability. *Id.* at 877-78. A statute that creates a substantial obstacle for a large fraction of those women affected by the regulation creates an undue burden and is facially unconstitutional. *See id.* at 894-95. Thus, in *Casey*, the Court rejected *Roe*'s trimester framework, but left intact a woman's fundamental right "to choose to have an abortion before viability and to obtain it without undue interference from the state." *Id.* at 846. In reaching this conclusion, the Court recognized that the state's

interests prior to viability "are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure." *Id.*

In *Casey*, the Supreme Court was presented with constitutional challenges to various provisions in a Pennsylvania statute governing informed consent, parental consent, record-keeping and reporting requirements, and a medical emergency exception. *See id.* at 844. Thus, the plurality opinion primarily focused on the state's legitimate interests in the potentiality of human life -- holding that to promote this "profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and measures designed to advance this interest will not be invalidated so long as their purpose is to persuade the woman to choose childbirth over abortion" and they do not impose an "undue burden on the right." *Id.* at 878.

Nevertheless, the *Casey* plurality also provided guidance by addressing the state's concomitant, and equally legitimate, interest in preserving and protecting the health of women seeking abortion services -- of particular relevance to the challenge in this case. Specifically, the *Casey* plurality held that as

> with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. *Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.*

Id. at 878 (emphasis added).

The types of burdens that may be imposed by state

regulation are varied in nature, but clearly include financial burdens which restrict or prohibit the exercise of the right. As noted by the *Casey* plurality:

> Numerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it. Only where the state regulation imposes an undue burden on a woman's ability to make the decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.

Id. at 874; *see also id.* at 901. Furthermore, "[n]ot all burdens on the right to decide whether to terminate a pregnancy will be undue." *Id.* at 876. As the *Casey* plurality noted:

> A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not to hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.

Id. at 877. Accordingly, the court must first determine

whether Regulation 61-12 furthers the state's interest in maternal health, which is the state interest the defendants contend Regulation 61-12 was designed to serve. *See id.*; *id.* at 900-01 ("The collection of information with respect to actual patients [which, under the statute at issue, will remain confidential] is a vital element of medical research, and so it cannot be said that the requirements serve no purpose other than to make abortions more difficult."). If Regulation 61-12 furthers the state's interest in maternal health, the court must next determine whether Regulation 61-12 imposes an undue burden on a woman's right to seek an abortion. *See id.* at 877, 901.

In this case, a careful review of the record discloses that Regulation 61-12 does not further the state's interest in maternal health. With respect to whether Regulation 61-12 furthers the state's interest in maternal health, I note that the Supreme Court has not provided much guidance in this area. However, several pre-*Casey* cases do provide some insight. For example, in *Roe*'s companion case, *Doe v. Bolton*, the Court invalidated a Georgia law requiring that all first trimester abortions be performed in a licensed hospital where the state failed to show that only the hospital environment could ensure the quality of the operation and the protection of the patients. *See* 410 U.S. at 195.

In *Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416 (1983), the Supreme Court was presented with a challenge to an Ohio ordinance which, among other things, required all second trimester abortions to be performed in a hospital. *See id.* at 422. Reaffirming the prohibition against over regulation of a relatively safe surgical procedure, the Court held that the

> [s]tate's discretion to regulate on [the basis of maternal health] does not ... permit it to adopt abortion regulations that depart from accepted

> medical practice.... If a State requires licensing or undertakes to regulate the performance of abortions during this period, the health standards adopted must be legitimately related to the objective the State seeks to accomplish.

Id. at 431 (citation and internal quotation marks omitted). The Court then invalidated the ordinance, holding that it "imposed a heavy, and unnecessary, burden on a woman's access to a relatively inexpensive, otherwise accessible, and safe abortion procedure." *Id.* at 438.[17]

From the above discussion, it is evident that the State of South Carolina has a legitimate interest from the outset of pregnancy in protecting the health of women seeking abortions, and that this interest is sufficiently important to allow the state to regulate abortion providers, including providers that limit their services to abortions during the first trimester. *See Casey*, 505 U.S. at 876. Furthermore, this interest allows the state to regulate, within the boundaries of *Casey* and its predecessors, such matters as the qualifications of the person performing the procedure, the facilities in which the abortions are performed, and the availability of medical care after the procedure and in the event of an emergency. *See Roe*, 410 U.S. at 149-50. However, *Casey* and its predecessors teach us that health regulations which are unnecessary, *i.e.*, not reasonably related to maternal health or which depart from accepted medical practice, cannot withstand constitutional scrutiny and must be invalidated. *See Casey*, 505 U.S. at 878; *Akron*, 462 U.S. at

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[17] The Supreme Court in *Casey* overruled only those parts of *Akron* that were "inconsistent with *Roe*'s statement that the state has a legitimate interest in promoting the life or potential health of the unborn." *Casey*, 505 U.S. at 870. Thus, the *Akron* decision continues to inform us as to the propriety of regulations purportedly enacted to further the state's interest in maternal health.

431.

In my view, Regulation 61-12 is riddled with unnecessary requirements, *i.e.*, requirements not reasonably related to maternal health or which depart from accepted medical practice. For example, Regulation 61-12's requirement that each abortion patient be tested for particular sexually transmitted diseases is not an accepted medical practice where there are no symptoms or other accepted medical reasons or risk factors to justify such a test.[18] Also, Regulation 61-12 requires an abortion clinic to perform urine pregnancy tests on all abortion patients, including those whose pregnancy have been confirmed by other means, *e.g.*, ultrasound. In addition, Regulation 61-12 places medically unnecessary administrative requirements on abortion clinics which are clearly inappropriate to medical offices of such small sizes as the plaintiffs' offices. For example, DHEC has mandated -- without regard to the number of staff or size of the abortion clinic -- the development of extensive policies and procedures, frequent staff meetings, formal in-service training and required staff certifications, and medical testing of employees which, while probably appropriate for a hospital or a large outpatient surgical center, are unnecessary in a small physician's office or clinic. Furthermore, there is no evidence in the record demonstrating how Regulation 61-12's construction and design requirements will further the health of women seeking abortions in South Carolina, and no explanation is offered as to why all of these requirements are so much greater for these clinics than they are for other physicians' offices performing the same type of procedures.

Another requirement which is not an accepted medical

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[18] In the district court, the defendants argued that selected diseases are more prevalent in women seeking abortions or that abortion clinics present a public health problem in this regard. However, the district court found insufficient credible evidence to support such a finding.

practice is Regulation 61-12's requirement that a registered nurse, as opposed to a licensed physician, supervise nursing care. There is no evidence in the record to suggest that a physician is not capable of supervising nursing care. In addition, Regulation 61-12 requires that an abortion clinic "be kept ... free from odors" and that all outside areas "be kept free of rubbish, grass, and weeds that may serve ... as a haven for insects, rodents and other pests." S.C. Code Ann. Regs. 61-12, §§ 604 and 606. However, there is no evidence in the record suggesting that these requirements would ensure the quality of a first trimester abortion procedure or the protection of patients.

The same can be said about Part X of Regulation 61-12 which grants DHEC the authority to impose penalties for any condition which, while not mandated or prohibited by Regulation 61-12, DHEC deems to be "against the best practices" as later defined by DHEC. *Id.* Part X. Obviously, Part X of Regulation 61-12 subjects physicians to unnecessary uncertainty in the operation of their practices and invites arbitrary enforcement. Finally, it is not an accepted medical practice to permit a state agency, such as DHEC, to enter an abortion clinic, copy records, and disseminate them publicly, but this is precisely what Regulation 61-12 allows.[19]

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[19] The majority implies that Regulation 61-12 requires DHEC to treat all abortion patient records as confidential. *See ante* at 23-24. However, Regulation 61-12 imposes no such requirement on DHEC. Rather, under Regulation 61-12, only the abortion clinic must treat patient records as confidential. *See* S.C. Code Ann. Regs. 61-12, § 402. Succinctly put, Regulation 61-12 allows DHEC to enter an abortion clinic, inspect its records, and make photocopies of these records, *see id.* § 102(F), and Regulation 61-12 places no limitation on DHEC's use of the records once photocopies are made. Thus, Regulation 61-12 differs markedly from the provisions upheld by the Supreme Court in *Whalen v. Roe*, 429 U.S. 589 (1977), and *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976), two cases cited by the majority. *See ante* at 23-24. In each of these cases, the statute at issue required the state agency which had access to the patient

In summary, Regulation 61-12 does not further the state interest of protecting maternal health. In fact, Regulation 61-12 has the opposite effect. As found by the district court, Regulation 61-12 will substantially increase the cost of abortions in South Carolina because Regulation 61-12 requires unnecessary tests be performed, unnecessary staff be hired, and, in some cases, extensive renovations to existing facilities be made. Because Regulation 61-12 will result in a substantial increase in the cost of obtaining an abortion in South Carolina, a significant number of women will be forced to either delay having an abortion, or forego having one altogether. This, in turn, will result in increased health risks to women seeking abortions. Accordingly, Regulation 61-12 serves no other purpose than to make abortions more difficult to obtain, and, therefore, Regulation 61-12 violates the Due Process Clause of the Fourteenth Amendment. *See Casey*, 505 U.S. at 877; *id.* at 900-01.

The majority concludes that Regulation 61-12 was designed to further the State of South Carolina's interest in

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records to treat the records as confidential and/or significantly limited the state agency's use of the patient records. *See Whalen*, 429 U.S. at 594 (New York statute had extensive measures to insure records remained confidential and provided that the public disclosure of the identity of patients was expressly prohibited); *Danforth*, 428 U.S. at 79-81 (Missouri statute mandated that patient information required on patient forms was confidential and to be used only for statistical purposes). In my view, Regulation 61-12 is more akin to a provision of a Pennsylvania statute rejected by the Supreme Court in *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986); in that case, even though the Pennsylvania law under review stated that patient reports were not public records, Pennsylvania law permitted the reports, which contained both information about the women who obtained abortions and information about the doctors who performed them, to be made public and also did not limit the Commonwealth's use of patient information. *See id.* at 764-68. One other point on the issue of confidentiality is worth noting. Both the guidelines of the NAF and ACOG prohibit the release of any medical record without the patient's consent

maternal health largely on the basis that Regulation 61-12 is generally compatible with accepted medical practice governing abortions, more specifically, the guidelines promulgated by ACOG and NAF. *See ante* at 17-20. The majority's analysis ignores the significant departures that Regulation 61-12 makes from those guidelines, the attendant costs associated with those departures, and the effect of those costs on the availability of abortions in the State of South Carolina. Regulation 61-12 goes far beyond the recommendations of ACOG and NAF, and, in some cases conflicts with them. Thus, while the ACOG and NAF guidelines address physical plant and equipment needs in abortion clinics, they do not suggest or support the extensive plant and equipment requirements (such as mandating numerous separate rooms or areas, utility sinks, and specific air exchanges, sheltered entryways, special janitor's closets) included in Regulation 61-12. Similarly, the ACOG and NAF guidelines do not contain any recommendations supporting the staffing requirements imposed by Regulation 61-12. For example, none of the guidelines require that a registered nurse supervise nursing care in an abortion facility if the attending physician is able to supervise that care. In addition, the ACOG and NAF guidelines do not support the testing requirements imposed by Regulation 61-12; specifically, they do not call for any routine testing of abortion patients other than for Rh factor and anemia, and they state that sexually transmitted disease testing should be performed on the basis of risk factors. Likewise, while the ACOG guidelines address the administration of abortion clinics, they do not require the extensive written policies, procedures, and formal meetings required by Regulation 61-12. Also, the ACOG and NAF guidelines forbid the release of any medical information from a patient's record without the prior consent of the patient, thus conflicting with Regulation 61-12's mandate that abortion providers permit DHEC to copy and remove patient records. In addition, while the ACOG and NAF guidelines recommend that

counseling be offered, Regulation 61-12 requires something very different. It mandates the establishment of relationships with outside specialists in various areas to whom patients can be referred. Finally, it should be noted that the district court found as a fact that the ACOG and NAF guidelines were just that, guidelines. They are not mandates.

The upshot of this discussion is that the departures from the ACOG and NAF guidelines listed above, coupled with many others not discussed, result in a substantial increase in the cost of obtaining an abortion in the State of South Carolina. As noted above, because Regulation 61-12 will result in a substantial increase in the cost of obtaining an abortion in South Carolina, a significant number of women will be forced to either delay having an abortion, or forego having one altogether. Also, the costs will likely force the closure of Dr. Lynn's Beaufort office, which will result in the elimination of abortion services in that part of South Carolina. Under such circumstances, one must conclude that Regulation 61-12 does not further the State of South Carolina's interest in maternal health.

Even if Regulation 61-12 furthers the state interest of protecting and preserving the health of women seeking abortions, Regulation 61-12 cannot stand if it imposes an undue burden on a woman's fundamental right to obtain an abortion, *see id.* at 877-78, as a regulation which has "the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." *Id.* at 877. A review of the record makes it clear that Regulation 61-12 will impose an undue burden on the right to obtain an abortion prior to viability. As noted earlier, a first trimester suction curettage abortion in South Carolina currently costs between $325 and $480, depending on the gestational age, the type of sedation or anesthesia needed, and the medical testing indicated. Based on the costs of complying with Regulation 61-12, the

district court found that Regulation 61-12 would raise the cost of each abortion performed by the plaintiffs in the following ranges: (1) for CWMC, the cost will increase between $36.48 and $75.03; (2) for Dr. Lynn's Greenville practice, the cost will increase between $93.09 and $170.39; (3) for Dr. Lynn's Beaufort practice, the cost will increase between $115.67 and $367.50; and (4) for GWC, the cost will increase between $22.68 and $32.39. *See Greenville Women's Clinic*, 66 F. Supp. 2d at 717. A significant increase in the cost of obtaining an abortion alone can constitute an undue burden on the right to have an abortion. *See Casey*, 505 U.S. at 901 ("While at some point increased cost could become a substantial obstacle, there is no such showing on the record before us."). It follows that the decreased availability of abortions due to the closure of the only abortion clinic in one area of a state also constitutes an undue burden on the right to have an abortion, as it increases the distance a woman has to travel to obtain an abortion, thereby significantly increasing the time and the cost to obtain an abortion.

Regulation 61-12 will impose a significant increase in the cost of obtaining an abortion in South Carolina, which, in turn, will prevent woman from obtaining abortions. For example, for a woman in Beaufort, South Carolina, the cost of a first trimester abortion will increase, at a minimum, $115.67, or, if Dr. Lynn's Beaufort practice closes because of Regulation 61-12, it may result in the elimination of abortion services in that part of the state altogether. Also the increased costs of providing abortions resulting from Regulation 61-12 at other facilities throughout South Carolina will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining an abortion, thus, resulting in increased health risks to women in South Carolina.

Regulation 61-12 also imposes additional burdens,

unrelated to cost, on the right to obtain an abortion. For example, Regulation 61-12 grants DHEC inspectors the right to inspect abortion clinics at will and without limitation; such inspections can be initiated by anonymous complaints. During any such inspection, DHEC inspectors are granted the right to copy confidential patient records, and Regulation 61-12 does not ensure that DHEC will keep these records confidential. Obviously, this requirement would have a chilling effect on a woman's freedom to choose to have, and a physician's willingness to preform, an abortion. Another example is Regulation 61-12's requirement that a married abortion patient disclose her husband's name. Obviously, this requirement is not necessary for the provision of safe medical care, and there are a host of reasons why a married patient would prefer not to disclose her husband's name. *Cf. Casey*, 505 U.S. at 893-98 (holding that Pennsylvania law requiring spousal notification prior to abortion imposes an undue burden on the right to have an abortion). Thus, this requirement also hinders a woman from obtaining an abortion. Finally, physicians performing five or more first trimester abortions per month must be licensed by the State of South Carolina and be "properly qualified by training and experience to perform" abortions. S.C. Code Ann. Regs. 61-12, § 205(C). However, Regulation 61-12 provides no guidance on the additional credentials required beyond that of a medical license to meet this qualification standard. Thus, physicians who perform five or more first trimester abortions per month operate under a constant fear that they will be declared "unqualified" by DHEC under some vague and amorphous standard. Obviously, this readily apparent fear would have a chilling effect on a physician's willingness to perform an abortion, thus, resulting in an adverse impact on a woman's ability to obtain an abortion. *Cf. Stenberg*, No. 99-830, 2000 WL 825889, at *19 ("In sum, using this law some present prosecutors and future Attorneys General may choose to pursue physicians who use D&E procedures, the most commonly used method for performing previability second

trimester abortions. All those who perform procedures using that method must fear prosecution, conviction, and imprisonment. The result is an undue burden upon a woman's right to make an abortion decision."). Under these circumstances, I am simply constrained to conclude that Regulation 61-12 imposes an undue burden on a woman's fundamental right to obtain an abortion. *Cf. Ragsdale v. Turnock*, 841 F.2d 1358, 1373-74 (7th Cir. 1988) (invalidating portions of a similar licensure regulation which mandated, among other things, detailed physical plant requirements, policies and procedures, and staffing requirements); *Birth Control Ctrs., Inc. v. Reizen*, 743 F.2d 352, 364-65 (6th Cir. 1984) (invalidating detailed, specific regulatory criteria governing the physical layout of abortion facilities, staffing requirements, and equipment requirements).

In its opinion, the majority concludes that Regulation 61-12 does not constitute an undue burden on a woman's right to obtain an abortion. *See ante* at 20-24. The pillar supporting the majority's holding is its observation that the plaintiffs failed to produce evidence demonstrating that the cost increases resulting from the promulgation of Regulation 61-12 would have an adverse effect on a women's ability to obtain an abortion in South Carolina. *See ante* at 22-23. This pillar is a transparent facade, at best.

In part, the district court's finding of an undue burden was premised on the testimony of the plaintiffs' expert, Dr. Stanley Henshaw. Dr. Henshaw testified that an increase of just $25 can be expected to prevent one or two out of every 100 low-income women seeking an abortion from being able to obtain one. Under Supreme Court case law, this constitutes an undue burden on a woman's right to obtain an abortion. *See Casey*, 505 U.S. at 894-95, (invalidating law that imposed substantial obstacle on a large fraction of the one percent of abortion patients who are married and do not

voluntarily notify their spouses of the abortion).

Moreover, the cost increases resulting from Regulation 61-12 will likely force Dr. Lynn to close his Beaufort practice. While traveling seventy miles on secondary roads may be inconsequential to my brethren in the majority who live in the urban sprawl of Baltimore, as the district court below and I conclude, such is not to be so casually addressed and treated with cavil when considering the plight and effect on a woman residing in rural Beaufort County, South Carolina.[20]

B

The Equal Protection Clause states in relevant part that no state shall "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. The Equal Protection Clause requires that "all persons

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[20] The majority seems to intimate that an increase in the cost of obtaining an abortion effectuated by the promulgation of a health regulation is irrelevant to the undue burden calculus. *See ante* at 22. According to the majority, to hold otherwise "would necessitate the formulation of an arbitrary cost threshold beyond which a price increase may not pass." *Id.* at 23. This, in turn, "would irrationally hamstring the State's effort to raise the standard of care in certain abortion clinics ... simply because the clinics' performance falls so far below appropriate norms that the expense of upgrading their practices and equipment exceeds the arbitrarily defined amount." *Id.* at 23. Unlike the majority, I believe that an increase in the cost of having an abortion effectuated by the promulgation of a health regulation is highly relevant to the undue burden inquiry. First, in *Casey*, the Supreme Court noted that a significant increase in the cost of obtaining an abortion alone can constitute an undue burden on the right to have an abortion. *See Casey*, 505 U.S. at 901 ("While at some point increased cost could become a substantial obstacle, there is no such showing on the record before us."). Second, the Supreme Court stated in *Casey* that a statute which, while furthering a state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends. *See id.* at 877.

similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432 (1985). However, the Equal Protection Clause's "promise that no person shall be denied the equal protection of the laws must coexist with the practical necessity that most legislation classifies for one purpose or another, with resulting disadvantage to various groups or persons." *Romer v. Evans*, 517 U.S. 620 (1996). Accordingly, "if a law neither burdens a fundamental right nor targets a suspect class," the legislation will be upheld "so long as it bears a rational relation to some legitimate end." *Id.*

Initially, it must be determined what level of scrutiny should be applied to the classifications at issue, which are physicians and abortion clinics that perform five or more abortions per month. The plaintiffs urge the court to apply strict or heightened scrutiny because the classifications penalize the exercise of the fundamental right to have an abortion or, at a minimum, target a suspect or quasi-suspect class. On the other hand, the defendants contend that physicians do not constitute a suspect class for equal protection purposes and do not have a fundamental right to perform abortions. Accordingly, the defendants argue that the court should apply the rational basis test.

Courts addressing the constitutionality of similar types of health care regulations have reached various conclusions under different tests. For example, in *Friendship Medical Center, Ltd. v. Chicago Board of Health*, 505 F.2d 1141 (7th Cir. 1974), the court invalidated abortion service regulations promulgated by the Chicago Board of Health which sought to regulate such things as the design of the medical facility, the type of medical staff and its training, the maintenance of equipment, supplies, and medications, the content of medical records, and the types of medical tests which must be administered to abortion patients. *See id.* at 1152-53. Applying strict scrutiny, the court invalidated the regulation

on both due process and equal protection grounds, because fundamental rights were involved. *See id.* at 1148-52. With regard to the equal protection analysis, the court held as follows:

> Given the Supreme Court's acceptance of the medical fact that the mortality rate of women receiving legal abortions is "as low as or lower than the rates of normal childbirth," ... there would seem to be little justification for extensive governmental regulations, purportedly based on health considerations, for one procedure than the other....
>
> The Chicago Board of Health's Rules on Abortion Services regulate comprehensively physicians who perform abortions, while at the same time leaving other medical procedures, often much more complex and dangerous in terms of the patient's health, up to the good judgment of the physician.

Id. at 1152 (quoting *Roe*, 410 U.S. at 149). Because the defendants offered no sufficiently compelling reason to justify the difference in treatment, the court invalidated the regulations. *See id.* at 1153. It had previously noted, however, that "on the record before th[e] court there is no basis for determining whether the regulations are even reasonably related to a valid state concern." *Id.* at 1150.

The Sixth Circuit has also been called upon to address comprehensive health regulations on several occasions. First, in *Mahoning Women's Center v. Hunter*, 610 F.2d 456 (6th Cir. 1979), *vacated on other grounds*, 447 U.S. 918 (1980), the court affirmed the district court's decision to invalidate, under the strict scrutiny test, a city ordinance imposing costly medical and building code requirements on first trimester abortion clinics, while leaving unregulated the performance of other medical and surgical procedures. *See*

id. at 460-61.

Next, the Sixth Circuit addressed the constitutionality of a Michigan licensing scheme which required all free-standing surgical outpatient facilities (FSOFs) to comply with staffing, structural, equipment, counseling, consent, and record-keeping requirements in order to obtain a license to operate. *See Birth Control Ctrs., Inc.*, 743 F.2d at 357. Because the licensing scheme applied to abortion clinics, albeit not exclusively, four abortion clinics challenged the scheme on equal protection grounds because it exempted private physicians' offices where abortions were performed. *See id.* at 356-57. The court affirmed the district court's application of the rational basis test as the appropriate standard of review, because the "differentiation between FSOFs and physicians' private offices did not involve any suspect class nor implicate any fundamental right." *Id.* at 358. In particular, the court held that "no suspect classification was involved ... since the state ha[d] chosen to regulate all FSOFs, not just abortion clinics," and distinguished *Mahoning* on this basis. *Birth Control Ctrs., Inc.*, 743 F.2d at 358 & n.4.

Finally, *in Women's Health Center of West County, Inc. v. Webster*, 871 F.2d 1377 (8th Cir. 1989), the Eighth Circuit, applying the rational basis test, upheld an abortion regulation which required emergency backup care against an equal protection challenge. *See id.* at 1381. The court noted that, although the regulation applied only to abortion providers, the state already required such backup care for all patients undergoing any outpatient surgery. *See id.* Thus, the regulation was a reasonable means of insuring the health of women seeking abortions and did not impose a special requirement upon abortion providers. *See id.*

It is unnecessary for me to decide whether the strict scrutiny test or the rational basis test should be applied in this

case because Regulation 61-12 is constitutionally infirm under the more lenient rational basis test. Under the rational basis test, the court must determine the relation between the classification adopted and the objective to be attained. *Romer*, 517 U.S. at 632. "The search for the link between classification and objective gives substance to the Equal Protection Clause; it provides guidance and discipline for the legislature, which is entitled to know what sorts of laws it can pass; and it marks the limits of our own authority." *Id.* "By requiring that the classification bear a rational relationship to an independent and legitimate legislative end, we ensure that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." *Id.* at 633. Furthermore, even if the disadvantaged group does not rise to the level of a suspect class entitled to the application of strict scrutiny, the court must closely scrutinize laws that disadvantage a politically unpopular group because such laws "raise[ ] the inevitable inference that the disadvantage imposed is born of animosity toward the class of persons affected." *Id.* at 634. "'[I]f the constitutional conception of "equal protection of the laws" means anything, it must at the very least mean that a bare ... desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest.'" *Id.* at 634-35 (quoting *Department of Agric. v. Moreno*, 413 U.S. 528, 534 (1973)).

The defendants contend that Regulation 61-12 does not violate the Equal Protection Clause because its provisions are rationally related to the legitimate state interest of protecting the health and welfare of women seeking abortions in the state. I disagree.

Obviously, South Carolina has a legitimate interest in protecting the health and welfare of women seeking abortions in the state. South Carolina also has a legitimate interest in promulgating uniform, minimum standards for the performance of surgical procedures, including first trimester

abortions. And South Carolina could constitutionally require that abortions only be lawfully performed by physicians licensed by the State Board of Medical Examiners to practice medicine pursuant to such uniform, minimum standards, thereby addressing any concern that unqualified, unlicenced physicians will come within its borders and establish unregulated abortion clinics performing unsafe abortion procedures.

However, as the district court noted,

> [t]he regulation singles out physicians and clinics where abortions are performed regularly, as part of the normal course of business and in relatively large numbers, and imposes upon them requirements which are not imposed upon comparable procedures and not even upon all physicians who perform first trimester abortions. In addition, the regulation's requirements reach far beyond those justified by actual differences in the procedure, or by the medical nature and risks of the procedure....
>
> Furthermore, defendants have offered no satisfactory explanation as to why the state standards applied to physicians' offices and clinics performing comparable procedures would not suffice to regulate first trimester abortion providers or ensure the health, safety and welfare of patients seeking abortions -- much less an acceptable basis for excluding physicians and facilities which perform first trimester abortions on a more infrequent basis....
>
> Regulation 61-12 singles out all physicians and clinics who perform more than the occasional first trimester abortion and requires of them a license to operate their office or clinic. To obtain the license, the physicians and clinics must comply with

> comprehensive mandates governing the physical layout of the clinic or office, the medical equipment which must be purchased and maintained, the cleaning, maintenance, and operation of the clinic and the requisite equipment, the management and training of the staff, and the type of medical care and tests which must be administered and offered to the patients. The onerous, and largely unnecessary, requirements of this regulation are neither "narrow enough in scope [nor] grounded in a sufficient factual context for [the court] to ascertain that there existed some relation between the classification and the purpose it is now alleged to serve."

Greenville Women's Clinic, 66 F. Supp. 2d at 742-43 (quoting *Romer*, 517 U.S. at 632-33).

In summary, Regulation 61-12 singles out and places additional and onerous burdens upon abortion providers which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions. Rather, "its sheer breadth is so discontinuous with the reasons offered for it that [Regulation 61-12] seems inexplicable by anything but animus toward the class that it affects." *Romer*, 517 U.S. at 632. The fact that Regulation 61-12 was directed towards a politically unpopular group in the absence of any existing public health problem only bolsters this conclusion.[21] *See id.* at 632-34.

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[21] Although the South Carolina legislature directed DHEC to regulate abortion facilities which performed five or more first trimester abortions per month, while leaving other licensed physicians under the exclusive supervision of the Board of Medical Examiners, it is undisputed that DHEC retained the discretion to refrain from treating abortion clinics and abortions differently than comparable facilities and procedures. For example, DHEC could have treated abortion clinics like other physicians' offices and clinics by promulgating regulations consistent with what is

III

The only remaining issue in the case is the question of severability. The defendants contend that the district court erred in refusing to sever the unconstitutional portions of Regulation 61-12 from the constitutional portions. This argument is without merit.

Whether Regulation 61-12 is subject to the doctrine of severability is a question of state, rather than federal, law. *See Department of Treasury v. Fabe*, 508 U.S. 491, 509-10 (1993). Under South Carolina law,

> [t]he test for severability is whether the constitutional portion of the statute remains complete in itself, wholly independent of that which is rejected, and is of such a character as it may fairly be presumed that the Legislature would have passed it independent of that which is in conflict with the Constitution.

Thayer v. South Carolina Tax Comm'n, 413 S.E.2d 810, 815 (S.C. 1992) (citation and internal quotation marks omitted). Moreover, if the statutory or regulatory scheme does not

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already required in physicians' offices by other laws and accepted standards. As to the physical plant requirements of Regulation 61-12, DHEC could have adopted regulations requiring the abortion clinic to meet all applicable building codes. As to staff qualifications and medical records, DHEC could have required the supervising physician to hire staff and maintain medical records that, in his or her professional discretion, would appropriately provide for the needs and rights of the patients. On the other hand, with regard to needs *unique* to the abortion procedure, DHEC could have treated abortion providers differently from other physicians' offices and clinics, but only based on actual differences between those facilities. Instead, DHEC placed onerous burdens upon abortion providers which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions.

contain a specific severability clause, the legislature or agency is presumed to have "intended the act to be effected as an entirety or not at all." *South Carolina Tax Comm'n v. United Oil Marketers, Inc.*, 412 S.E.2d 402, 405 (S.C. 1991).

Applying this standard, I conclude that Regulation 61-12 is not a proper candidate for severance. Regulation 61-12 does not contain a severability provision, despite the fact that other DHEC regulations have included such provisions. *See, e.g.*, S.C. Code Ann. Regs. 61-4, Part VI, § 601 (controlled substances regulation); S.C. Code Ann. Regs. 61-21, § T (sexually transmitted diseases). The absence of a severability clause is consistent with the scheme of the enabling legislation and the nature of the regulation. It is apparent that the South Carolina legislature intended for DHEC to create a comprehensive licensing scheme for abortion providers, as Regulation 61-12 sets forth areas to be addressed by the regulation as a whole, and the text of the regulation is comprehensive and interdependent, reflecting a similar intent that it stand or fall as a whole. In other words, because the South Carolina legislature directed DHEC to promulgate a comprehensive set of regulations governing virtually every aspect of the abortion procedure, it is evident that the South Carolina legislature intended for all of Regulation 61-12 to be enforced or none of it. Finally, I note that severance is simply not possible, as I am simply unable to "untangle the constitutional from the unconstitutional provisions." *Ragsdale*, 841 F.2d at 1375.

IV

I have some final comments concerning Part IV of the majority opinion. The accusatory tone of this portion of the majority opinion, aimed at me and the district judge who decided the case below, can only evince a majority which refuses to recognize that current Supreme Court precedent mandates that a woman still has the fundamental right to

obtain an abortion. In its eagerness to uphold any impediment to a woman's fundamental right to a previability abortion, the majority, interjecting the emotional and psychological aspect of a woman's decision, would desensitize the real and basic issue to be addressed when evaluating such regulations -- that is, whether the regulations are medically necessary and, if so, whether the regulations impose an undue burden on a woman's fundamental right to have an abortion at the previability stage of pregnancy. There is no doubt that the State of South Carolina can, within limits, treat abortions differently from other medical procedures. But to resolve the question of whether regulations governing abortions are medically necessary, some reference to comparable procedures is necessary, if not inevitable.

When considering the majority's analysis based on its chosen and carefully selected facts, ignoring the findings of fact by the district court, it can only be concluded that the majority's opinion is based on its view of the law as it would like to see it and, perhaps more significantly, on not what the current law would dictate, but only what the majority prophecies the law will be if and when this case reaches the Supreme Court. This is simply unacceptable; cases are to be decided on what the law is. It's just that simple.

To sum up, Regulation 61-12 is violative of the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and, under South Carolina law, Regulation 61-12 is not subject to the doctrine of severability. Accordingly, I would affirm the judgment of the district court.[22]

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[22] With regard to the argument of the defendants attacking the district court's award of attorneys' fees, the argument is without merit.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

No. CIV A 6:96-1898-21

GREENVILLE WOMEN'S CLINIC, CHARLESTON WOMEN'S MEDICAL CLINIC, INC., and WILLIAM LYNN, M.D., on behalf of themselves and their patients seeking abortions,

Plaintiffs,

v.

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control, the Governor of the State of South Carolina, in his official capacity, and CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina,

Defendants.

O-R-D-E-R

This matter is before the court pursuant to a lawsuit filed by a physician and two medical clinics which offer first trimester abortion services in South Carolina, challenging the constitutionality of a state regulation, S.C. Code Ann. Regs. 61-12, which governs the licensure and operation of physicians' offices and abortion clinics that perform five or

more first trimester abortions per month. Plaintiffs seek a declaration that the regulation is unconstitutional and injunctive relief against state officials who would enforce it.

On July 19, 1996, this court issued an order granting plaintiffs' motion for a temporary restraining order and enjoining defendants from enforcing the challenged regulation, pending a hearing on the issuance of a preliminary injunction. Prior to such hearing, however, the parties notified the court that they had agreed to continue the injunction until a decision could be rendered on the merits. A six day non-jury trial was held before this court beginning July 13, 1998, and arguments were heard on October 9, 1998.

INTRODUCTION

In 1973, the Supreme Court of the United States ruled that a woman's decision to have an abortion was a fundamental right protected by the Constitution. Because the South Carolina Department of Health and Environmental Control, ("DHEC"), has promulgated a regulation governing abortions and abortion clinics, and because there is a legal challenge to its requirements, it has become the responsibility of this court to examine the regulation to determine if it can withstand a challenge to its constitutionality.

An analysis of this issue begins not only with an understanding that a woman's right to choose to undergo an abortion is a constitutionally protected one, but also with a recognition that a state has a legitimate interest in regulating abortions in order to protect maternal health and to promote fetal life. A state has a duty to protect its citizens and this court will uphold such efforts so long as a state's laws do not tread improperly upon rights protected by the United States Constitution.

In this case, DHEC has promulgated a regulation in the

area of abortions which it clearly had the right to do. What it did wrong was to go too far. Despite the fact that abortion clinics have been operated in a safe manner for the past twenty-three years, DHEC loaded these abortion clinics down with so many unnecessary requirements that the court has no choice but to conclude that the regulation unduly burdens a woman's fundamental right to undergo an abortion and, therefore, violates the Due Process Clause of the Fourteenth Amendment to the Constitution.

The regulation also violates the Equal Protection Clause of the Fourteenth Amendment. Simply put, this regulation would impose severe requirements on physicians and clinics performing five or more abortions per month, but not on physicians and clinics performing four abortions per month and/or other, virtually identical, procedures. At trial, there was no logical reason offered as to why these two groups should be treated so differently.

As a result of the many problems with the regulation, this court is constrained to find that it is facially unconstitutional under the Fourteenth Amendment. This court has tried to sever the objectionable portions from the regulation, but the problems are so many and so diffuse that their omission would render the regulation unworkable. Consequently, this court has no alternative but to declare the regulation as a whole invalid and unenforceable.

FINDINGS OF FACT[1]

[1] Pursuant to Fed. R. Civ. P. 52(a), the court sets forth separate findings of fact and conclusions of law. This case involves so much detail, however, that occasionally a full presentation of the issues blurs the distinction between findings of fact and conclusions of law. Accordingly, the court notes that to the extent any of the findings of fact constitute conclusions of law, they are adopted as such, and to the extent any conclusions of law constitute findings of fact, they too are adopted as such.

A. The Parties

1. Plaintiff Greenville Women's Clinic ("GWC"), located in Greenville, South Carolina, is a women's health care clinic providing gynecological health services, including abortions through 14 weeks of pregnancy measured from the pregnant woman's last menstrual period ("lmp").[2] Dr. Terry Buffkin and Dr. Thomas Campbell own and operate GWC, which has been in operation since 1978. Both are physicians licensed to practice medicine in South Carolina and are board certified in obstetrics and gynecology. On average, GWC performs approximately 2,746 first trimester abortions per year.

2. Plaintiff Charleston Women's Medical Clinic, Inc. ("CWMC"), located in Charleston, South Carolina, is also a women's health care clinic providing gynecological health services, including abortions through 12.5 weeks of pregnancy lmp. CWMC has been in operation for approximately 25 years. Ms. Lorraine Maguire, a licensed practical nurse, is the administrator of CWMC, and Dr. Richard Manning is its medical director. Dr. Manning is licensed to practice medicine in South Carolina and is board certified in obstetrics and gynecology. The CWMC, on average, performs approximately 2,408 first trimester abortions per year.

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[2] During the course of trial, pregnancy was measured either from the date of the woman's last menstrual period or from conception, which is generally considered to occur two weeks after the woman's last menstrual period. Accordingly, 14 weeks lmp is equivalent to 12 weeks from the date of conception. See e.g., S.C. Code Regs. 61-12, Section 101(S)(1) and (4).

3. Plaintiff William Lynn, M.D. is a physician licensed to practice medicine in South Carolina and is board certified in obstetrics and gynecology. Dr. Lynn owns and operates two medical practices -- an office in Beaufort, South Carolina ("Dr. Lynn's Beaufort office") and an office in Greenville, South Carolina that does business as the Palmetto State Medical Center ("PSMC"). Dr. Lynn has been regularly performing abortions since 1980. As part of his practice, Dr. Lynn provides abortions up to 13.9 weeks lmp. On average, Dr. Lynn performs 407 first trimester abortions per year in Beaufort and 536 first trimester abortions per year in Greenville.

4. Defendants are Douglas E. Bryant, in his official capacity as Commissioner of the South Carolina Department of Health and Environmental Control ("DHEC"), the Governor of the State of South Carolina, in his official capacity, and Charles M. Condon, in his official capacity as Attorney General of the State of South Carolina.

B. The Challenged Regulation

5. Prior to 1995, the State of South Carolina only required licensing of physicians' offices or other facilities in which second trimester abortions were performed. See S.C. Code Ann. §§ 44-41-20(b) and 70(b) (Law Co-op 1985). On January 3, 1995, however, the South Carolina legislature amended Chapter 41 of Title 44 as follows:

> (A) A facility in which <u>any second trimester or five or more first trimester abortions</u> are performed in a month must be licensed by [DHEC] to operate as an abortion clinic and must comply with the

> provisions of Article 3 [the Woman's Right to Know Act].
>
> (B) The department shall promulgate regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to patient follow-up care necessary to carry out the purposes of this section.

S.C. Code Ann. § 44-41-75 (Law Co-op Supp. 1997) (emphasis added). The legislation is not challenged in this action.

6. Pursuant to this legislative directive, and procedures governing the promulgation of state regulations (the South Carolina Administrative Procedures Act ("APA"), S.C. Code Ann. § 1-23-10 et. seq. (Law. Co-op.1986 and Supp.1997)), DHEC officials drafted the challenged regulation, entitled "Standards for Licensing Abortion Clinics," S.C. Code Regs. 61-12. The regulation consists of approximately twenty-seven pages of detailed requirements that an abortion clinic must comply with in order to obtain and maintain a license to perform abortions, which is to be issued annually by DHEC. An abortion clinic is defined as "[a]ny facility, other than a hospital as defined in Section 101.J, in which any second trimester or five or more first trimester abortions per month are

performed." S.C. Code Regs. 61-12, Section 101.B.[3] Thus, it includes all abortion clinics, regardless of their ownership, as well as privately owned and operated physicians' offices. The regulation is divided into ten "Parts," as follows:

> Part I - Definitions and Requirements for Licensure;
>
> Part II - Administration and Management;
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> Part III - Patient Care;
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> Part IV - Medical Records and Reports;
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> Part V - Functional Safety and Maintenance;
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> Part VI - Infection Control and Sanitation;
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> Part VII - Fire Protection and Prevention;
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> Part VIII - Design and Construction;
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> Part IX - Prerequisites for Initial Licensure; and
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> Part X - General.

With the exception of Parts IX and X, each Part is in turn divided into several sections which impose detailed requirements for the clinic's physical plant,

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[3] A "Hospital" is defined as "[a]n institution licensed for hospital operation by the Department in accordance with the provisions of Article 3, Chapter 7, Title 44, of the S.C. Code of Laws, 1976, as amended, and that has been certified by the Department to be a suitable facility for the performance of abortion." S.C. Code Regs. 61-12, Section 101.J.

staffing, and provision of medical care. There is no severability clause contained within the regulation.

7. Currently, South Carolina does not require licensing of physicians' offices outside of the abortion context. Furthermore, physicians licensed to practice medicine in the state are not subject to DHEC regulation, but rather are governed by the South Carolina State Board of Medical Examiners. See S.C. Code Ann. § 40-47-5 et. seq. (Law Co-op.1986 and Supp.1997). The State Board of Medical Examiners handles the examination and licensure of physicians within the state, complaints against physicians, the suspension and revocation of licenses when appropriate, and the imposition of civil penalties and other sanctions against physicians. With the exception of standard building codes imposed by their particular locales, physicians' offices are not subject to any mandated design and construction requirements. Thus, physicians who limit their abortion practice to less than five first trimester abortions per month are exempt from the requirements of Regulation 61-12. See S.C. Code Ann. § 44-41-75(A); S.C. Code Regs. 61-12, Section 101.B. In addition, physicians who perform surgical procedures in their offices which are comparable in terms of risks and duration to first trimester abortions are not subject to the stringent requirements which Regulation 61-12 imposes upon those physicians who regularly perform abortions in their offices.

8. Plaintiffs contend that Regulation 61-12 violates the substantive due process rights of women seeking abortions in South Carolina because it was not designed to and does not further the state's interest in maternal health, and because the costly provisions will place an undue burden upon a woman's fundamental right to

obtain an abortion.[4] Plaintiffs also contend that Regulation 61-12 violates the Equal Protection Clause because it imposes burdensome and costly requirements upon licensed physicians who regularly perform first trimester abortions which are not imposed upon licensed physicians who perform either identical procedures in lesser numbers or comparable surgical procedures regardless of the frequency. In addition, plaintiffs contend that certain sections of the regulation are unconstitutionally vague, violate the confidentiality rights of patients undergoing the abortion procedure, and violate the Establishment Clause contained within the First Amendment.

C. Specific Requirements of the Challenged Regulation

9. Plaintiffs contend that the regulation as a whole is medically unnecessary and unduly burdensome to the providers of first trimester abortions in South Carolina and their patients. In addition, plaintiffs have raised individual challenges to specific sections of the regulation. The comprehensive nature of Regulation 61-12 renders a summary of its provisions a daunting task. What follows is a summary by categories created by the regulation, placing special attention on those portions upon which plaintiffs have focused this challenge.

10. Part I of the regulation sets forth general "Requirements

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[4] Although defendants asserted lack of standing as a defense in their answer, they have not pursued the defense during this litigation. Because Regulation 61-12 applies to first trimester abortion providers, the plaintiffs have standing to challenge the constitutionality of the regulation. See e.g., Virginia v. Am. Booksellers Ass'n, 484 U.S. 383, 392 (1988); Doe v. Bolton, 410 U.S. 179, 188 (1973); Friendship Med. Ctr., Ltd. v. Chicago Bd. of Health, 505 F.2d 1141, 1145-48 (7th Cir. 1974).

for Licensure" of abortion clinics. In order to operate, the facility must undergo a pre-licensure inspection. Once the initial license is obtained, the facility must be inspected annually in order to obtain renewal of the license. In addition, the regulation provides that the facility may be subjected to unannounced DHEC inspections at any time, during which DHEC "inspectors shall have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations." S.C. Code Regs. 61-12, Section 102.F.2. There is no requirement in the regulation that DHEC or its inspectors maintain the confidentiality of any records, including the patient's personal medical records, although DHEC has included such confidentiality directives in regulations governing other types of health care facilities. See e.g., S.C. Code Ann. Regs. 61-91, Section 1001-D (mandating that DHEC "safeguard[ ] information in the medical records [of patients in ambulatory surgical centers] against ... use by unauthorized persons").

11. Upon a determination by DHEC that a facility is in violation of "any statutory provision, rule or regulation relating to the operation or maintenance of such facility," DHEC may deny, suspend or revoke the license. S.C. Code Regs. 61-12, Section 103. In addition, DHEC may assess a monetary penalty for each violation up to $5000. The amount of the penalty is based upon the specific provision at issue, which has been preassigned a designation as either a Class I, II, or III violation. In addition to the detailed requirements already set forth in the regulation, the regulation also authorizes imposition of a Class III penalty for any practice deemed to be "against the best practices as interpreted by the Department," S.C. Code Regs. 61-12,

Section 103.C., without further guidance or definition.

12. Part II of the regulation governs "Administration and Management" of the clinic. Section 201 requires the facility to develop and implement detailed written policies and procedures for operation of the facility, which must include at a minimum policies and procedures to ensure compliance with all federal, state, and local laws which govern the facility; designation of a responsible person and the establishment of methods for holding the person responsible; personnel policies and procedures, including in-service training requirements; a facility-wide quality improvement program, including statistical summaries, and a written plan of implementation; a policy and procedure for patient rights and grievance procedures; functional safety and maintenance policies and procedures; a policy and procedure for incident reporting; and policies and procedures for obtaining informed consent from the patient.[5] In addition, the facility's policies and procedures must include a provision for annual review and evaluation of the facility's other policies and procedures, as well as for its management and operation. No specific guidance is provided as to what these policies and procedures must contain.

13. Section 203 requires the facility to maintain on file all current policies and procedures concerning operation of the facility, memoranda of agreements and credentialing documentation, a copy of the regulation, annual elevator safety inspections and an annual heating, ventilation, and air conditioning inspection report.

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[5] Informed consent for an abortion is already required by state law. See S.C. Code Ann. § 44-41-30 and § 44-41-310 et seq (Law Co-op Supp. 1997).

14. Section 204 sets forth detailed personnel requirements. The facility must obtain and verify professional and personal background information on every employee and must develop and implement a written orientation program for new staff members, to include orientation on the other policies and procedures. A formal, written, inservice training program must also be planned and provided for all employees and volunteers, and records kept of attendance. The inservice training of all employees and volunteers must include four specified areas -- infection control, fire protection, confidentiality and patient rights, and licensing regulations. Written job descriptions must be prepared and reviewed annually, and a personnel file containing various mandated information must be kept on all employees. Annually, each employee must have a tuberculin skin test or, if previously positive, a chest x-ray to determine whether tuberculosis is present. If tuberculosis is diagnosed, the facility must provide treatment and investigate employee contacts. Employees and volunteers are also banned from working if they have any infected wounds, boils, sores, acute respiratory infections, or any other contagious disease or illness. According to the medical evidence in this case, this would include such ordinary illnesses as a common cold. In addition, all professional and allied health professional staff members must be certified by the American Red Cross or American Heart Association as capable of performing CPR, although only one such certified person must be with patients when they undergo the abortion procedure and during the recovery period.

15. Section 205 sets forth requirements for the clinical staff, which encompasses all physicians, nurses, and allied health professionals. Abortions may only be

performed by physicians licensed to practice medicine in South Carolina who are also "properly qualified by training and experience to perform pregnancy termination procedures." S.C. Code Regs. 61-12, Section 205.C.1. The regulation, however, provides no guidance on the additional credentials required beyond that of a medical license to meet this qualification standard. The facility must also obtain and maintain signed, written agreements with at least one physician board certified in obstetrics and gynecology who has admitting privileges at a local hospital which provides obstetrical and gynecological services. All nursing care is required to be under the supervision of a registered nurse licensed in the State of South Carolina, regardless of the presence of a physician in the facility, and the registered nurse must be "on duty to provide or supervise all nursing care" during preparation, the procedure, recovery, and discharge. S.C. Code Regs. 61-12, Section 205.D.2. Licensed practical nurses may be employed so long as they work under the supervision and direction of a registered nurse. Ultrasounds may only be conducted by physicians or ultrasound technicians who have documented evidence of completion of a training course in ultrasonography. Finally, the entire clinical staff must participate in quarterly meetings to review and analyze clinical experiences, and minutes must be kept and maintained of each meeting.

16. Sections 206 through 208 of the regulation require the facility to comply with state statutory sections pertaining to the dissemination of information to women seeking abortions and to obtaining consent to perform the procedure, each of which already contains penalty provisions for the failure to comply. Thus, these portions of the regulation do nothing more that impose a second layer of penalties (indeed, the most

severe Class I penalties) for the conduct already punishable under the statutory sections incorporated within the regulation.

17. Section 209 of the regulation requires the facility to "have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with [DHEC]." S.C. Code Regs. 61-12, Section 209. A copy of the patient rights must be conspicuously displayed, and a copy must be signed by each patient and included in the patient's medical record. However, no guidance is provided as to what specific information must be included in these documents.

18. Part III of the regulation sets forth requirements for "Patient Care." Additional "patient care policies and procedures designed to ensure professional and safe care for patients" must be developed, S.C. Code Regs. 61-12, Section 301, and must include, but are not limited to, policies and procedures for admission criteria; physician and nurse responsibilities; details regarding the pre-operative procedures (including history and physical, special examinations, lab procedures and consultations which will be required, and ultrasonography procedures); details regarding the actual abortion procedure (including the use of IV's, fluids, analgesia, anesthesia, and tissue examination and disposal); details regarding post-procedure care and recovery room care, including emergency care; "[p]rovisions for education of the patient, family and others, as appropriate in pre and post-procedure care," S.C. Code Regs. 61-12, Section 301.F.; plans for follow-up care, including arrangements for a postoperative visit and specific instructions in the event of an emergency; procedures for the management and referral of high-risk conditions; procedures for the

transfer of patients when needed; procedures for infection control and sanitation (including duties and responsibilities of an infection control committee which are, in turn, charged with the responsibility of developing and implementing specific patient care and administrative policies to investigate, control and prevent infections in the facility); and procedures for the registration of fetal death or death certificates.

19. Section 303 of the regulation imposes detailed requirements concerning emergency drugs which must be kept on the premises, and specifies seven medical conditions for which drugs and equipment must be available. In addition, the regulation mandates the presence of a refrigerator with "[a] thermometer accurate to +/- 3 degrees Fahrenheit." S.C. Code Regs. 61-12, Section 303.C. A specific method of preparing medications for administration is mandated, including a requirement that a sink and counter be in the area.

20. Section 304 requires laboratory services to be performed in compliance with the requirements already mandated by the Clinical Laboratory Improvement Amendments of 1988, ("CLIA"), 42 U.S.C.A. § 263a (West 1991).[6] It further requires the physician to perform a urine pregnancy test (unless fetal heart beats or movements are identified on physical examination), a urinalysis which includes albumin and glucose examination, and a hematocrit or hemoglobin test. In addition, the physician must perform a test to determine Rh factor. If the patient is Rh positive, an additional Du variant test is required. Rh (D) immune globulin must be administered if the patient is determined to be Rh negative. Testing for chlamydia and gonorrhea is

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[6] The court notes, however, that CLIA-88 has been subsequently amended, see 42 U.S.C. § 263a (West Supp. 1998).

mandatory, but testing for syphilis serology and performance of a Papanicolaou (pap) smear must only be offered to the patient.

21. Section 305 provides additional requirements for emergency care. It requires that "[a]ll staff and/or consulting physicians" have admitting privileges at one or more local hospitals that provide appropriate obstetrical/gynecological services or have in place documented arrangements approved by DHEC for the transfer of emergency cases when hospitalization becomes necessary. S.C. Code Regs. 61-12, Section 305.A. The facility must maintain equipment and services to render emergency resuscitative and life-support procedures pending transfer. And the facility must notify, in writing, the local ambulance service of the location of the facility and the nature of the medical problems which may result from abortions.

22. Section 306 mandates that the facility purchase and maintain specific equipment and supplies, including such items as "[a] bed or recliner suitable for recovery," oxygen, mechanical suction, resuscitative equipment, emergency medications, intravenous fluids, "[a] clock with a sweep second hand," sterile suturing equipment and supplies, an adjustable examination light, and soiled linen and waste containers. S.C. Code Regs. 61-12, Section 306.

23. Section 307 mandates that the facility have "[a]rrangements ... for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed." S.C. Code Regs. 61-12, Section 307. The regulation does not specify whether the

"arrangements" must be in writing, nor does it specify the number of clergymen or types of religious counseling which must be made available.

24. Section 308, entitled "Quality Improvement," again mandates a written plan for a quality improvement program for patient care and designation of an individual responsible for coordinating the program. Specific requirements include ongoing monitoring and evaluation of "patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services." S.C. Code Regs. 61-12, Section 308.B. Evaluation of patient care is required to be "criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified," S.C. Code Regs. 61-12, Section 308.B, but the regulation does not specify what criteria are acceptable or required. The process must incorporate a quarterly review of a minimum of five percent of the medical records per quarter, and must include a means of obtaining input from families of patients if they are "involved in the care and services provided by the facility." S.C. Code Regs. 61-12, Section 308.E. The facility administrator must review the findings of the program and ensure corrective actions are taken. The program must also identify and establish indicators of quality care, specific to the facility, that must be monitored and evaluated. Annual review of the results is also required.

25. Part IV of the regulation sets forth requirements for "Medical Records and Reports." Section 401 begins by setting forth detailed requirements for the preparation and maintenance of medical records, which must include, at a minimum, twenty categories of

information. Of particular concern to the plaintiffs in this case, the section requires a face sheet with patient identification data, including the name of the patient's husband in addition to the name, address and telephone number of a person to be notified in the event of an emergency. The records are required to be kept confidential by the facility (although no such requirement is imposed upon DHEC inspectors who obtain them) and must be stored for a minimum of 10 years. Section 403 requires the preparation of additional reports, including a record of every accident or incident occurring in the facility which involves patients, staff, or visitors. If it results in serious injury, the accident or incident must be self-reported to DHEC. Serious injuries "include, but are not limited to," accidents and incidents that lead to hospitalization or death (other than of a fetus) and adverse drug reactions. S.C. Code Regs. 61-12, Section 403.B.

26. Part V of the regulation, entitled "Functional Safety and Maintenance" requires additional policies and procedures, including, but not limited to, safety rules and practices for personnel, equipment, gases, liquids, drugs, supplies, and services; provisions for investigating accidents on the premises; provisions for disseminating safety-related information to employees and users of the facility; provisions for syringe and needle handling and storage; and provisions for managing infections waste in accordance with another DHEC regulation already governing such matters. In addition, the facility must prepare and post a disaster preparedness plan for evacuation in the event of a fire or other emergency. All parts and portions of the facility are generically required to be kept "in good repair and operating condition," and "free of hazards." S.C. Code Regs. 61-12, Section 503.A. In addition, the section requires that "[a]ll wooden surfaces shall be

sealed with a non-lead based paint, lacquer, varnish, or shellac that will allow sanitization." Id. A written preventive maintenance program must be developed and implemented for patient monitoring equipment and tested in accordance with manufacturer's specifications, but not less than annually. Records of maintenance and testing must be kept.

27. Part VI of the regulation is entitled "Infection Control and Sanitation." It sets forth specific requirements for sterilization, including daily testing of the autoclave and a log of results, as well as periodic calibration and preventative maintenance as necessary, but not less than annually. The regulation contains provisions mandating "adequate" linens and "proper laundering," and provides that "[a] sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing." S.C. Code Regs. 61-12, Section 603. It specifically prohibits towel-sharing. The regulation also generically requires that the facility "be kept neat, clean, and free from odors," mandates specific requirements for cleaning methods to be used and prohibits others, and imposes requirements for refuse and waste disposal. S.C. Code Regs. 61-12, Sections 604 & 605. Section 606 requires that "[a]ll outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests," and that all "[o]utside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow, and other impediments." S.C. Code Regs. 61-12, Section 606.

28. Part VII of the regulation, entitled "Fire Protection and Prevention," provides detailed requirements for fire-fighting equipment and systems, an evacuation plan, training of employees in the evacuation plan,

mandatory fire drills at least once every three months, maintenance of fire equipment, and maintenance of records proving compliance with the provisions.

29. Part VIII of the regulation sets forth detailed requirements for the "Design and Construction" of abortion facilities. There is no grandfathering provision (unlike other DHEC regulations governing medical and patient care facilities) -- rather all facilities must be in full compliance within two years. The requirements are set forth in overwhelming detail, rendering a summary of them impossible. By way of example, however, the regulation governs the number and size of procedure and recovery rooms, specifies the design and equipment required in toilet rooms, regulates the direction of the "[a]ir flow" within the sterilization rooms, S.C. Code Regs. 61-12, Section 807.F., mandates a minimum width for doors and corridors, sets forth specific requirements for heating and air conditioning (the unit must be capable of maintaining a temperature between 72 and 76 degrees), regulates the facility's air supply and exhaust, regulates design criteria for clinic entrances, sets forth specific requirements for the "janitor's closets," S.C. Code Regs. 61- 12, Section 807.O., and specifies the corridor glazing materials, wall finishes, wall bases, and interior finish materials that must be present. The regulation also regulates water supply and plumbing within the facilities.

30. Part IX of the regulation sets forth additional "Prerequisites for Initial Licensure" of the facility, including plan and construction approval by DHEC, and specifies the documentation required to be submitted with the facility's initial application for licensure.

31. Finally, Part X of the regulation, entitled "General"

states in its entirety that "[c]onditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department." S.C. Code Regs. 61-12, Part X. As noted previously, a violation of such an unspecified requirement is considered a Class III violation of the regulation.

32. At the trial of the case, defendants sought to enter several "stipulations" concerning their intended interpretation of certain requirements of the regulation. First, as to Section 102.F.2., which grants DHEC inspectors the right to copy medical records without a confidentiality provision, defendants assert that DHEC "policy" would protect the confidentiality of these records, as would the provisions of S.C. Code Ann. §§ 44-7-310 and 315 (Law Co-op. Supp. 1997). Second, as to Section 307 which requires the facility to make "[a]rrangements" with various specialties, defendants contend that the section does not require written "agreements" with such specialties, but only that the physician attempt to assist the patient in obtaining a referral when such services are indicated and/or requested by the patient. Third, as to Section 205(C)(2) which requires the facility to enter into a signed written agreement with at least one physician board certified in obstetrics and gynecology (if one is not on staff) and who has admitting privileges at a local hospital, defendants sought to delete the board-certification requirement. Finally, as to Section 602.C.1 which requires daily autoclave testing, defendants admit this is an error and that it should be weekly testing. Plaintiffs have not joined in these "stipulations." Instead, they contend that defendants' proposals are efforts to rewrite the regulation.

D. Abortion Services in South Carolina

33. According to the evidence in this case, there are no abortion providers in South Carolina who perform elective abortions (those not associated with medical complications) in the second trimester of pregnancy. All of the plaintiffs in this action limit their services to abortions during the first trimester of pregnancy.

34. Plaintiffs in this case currently use the suction curettage procedure during the first trimester for elective abortions. The procedure is also utilized for spontaneous miscarriages. Although not wholly without risks, it is undisputed that a suction curettage abortion during the first trimester of pregnancy is a relatively safe and quick medical procedure performed between six and fourteen weeks lmp. It involves dilating the cervix, inserting a suction catheter into the uterus, and applying suction to remove the contents of the uterus. Although the patient is usually in the procedure room for a total of ten minutes, the procedure itself only takes approximately two to five minutes. It involves no incision and a minimum of bleeding. After the procedure, patients usually walk to the recovery area, where their pulse and blood pressure are monitored and they are checked for any abnormal bleeding. Possible complications from the suction curettage procedure are fainting from vasovagal response, uterine perforation, excessive bleeding, infection, and retained tissue in the uterus. However, while the total complication rate for the procedure is about 1 in 100, serious complications are rare. The rate for complications requiring hospitalization is only about 1 in 2000. And the mortality rate is 1 in 100,000, which is about 25 times less risky than carrying a pregnancy to term. There is no evidence in this case that a first trimester suction curettage abortion has ever

resulted in a woman's death in this state.

35. Physicians in South Carolina, including Dr. Buffkin and Dr. Campbell, also perform medical abortions to terminate pregnancies located outside the uterus (such as in the fallopian tube) during the first six to seven weeks of pregnancy. A medical abortion is an even safer procedure than the suction curettage. It involves the performance of a routine blood test to measure the patient's hormone levels, followed by the injection of a drug (methotrexate) into the patient's arm. There is no recovery time after the injection, and only mild vaginal bleeding. Follow-up care consists of rechecking the patient's hormone levels several days after the injection, and rechecks thereafter at seven day intervals. Although currently limited in use to the termination of ectopic pregnancies, methotrexate and a second drug, RU- 486, are currently being used in research protocols for use in terminating intrauterine pregnancies.

36. Regulation 61-12 applies to abortion clinics performing five or more first trimester abortions and/or a single second trimester abortion per month. It is undisputed that second trimester abortions are significantly more risky to the health of women than first trimester abortions. Because the plaintiffs in this case only provide abortions during the first trimester of pregnancy, plaintiffs' challenge to the regulation is limited to its application to providers of first trimester abortions in South Carolina. Accordingly, the court will express no opinion as to the constitutionality of Regulation 61-12 as applied to facilities which may seek to perform second trimester abortions in the future.[7]

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[7] Regulation 61-12 contains an additional section, Section 309 under Part III "Patient Care," which mandates additional qualifications which the

E. The Drafting and Promulgation of Regulation 61-12

37. At the trial of this case, several DHEC employees and a DHEC consultant testified concerning the drafting and promulgation of Regulation 61-12. The testimony reveals that the regulation was not tailored to further the state's legitimate interest in preserving and protecting the health of women seeking first trimester abortions and that the drafters took no meaningful steps to ensure that it would serve that purpose. Nor did they attempt, in any meaningful fashion, to determine the financial impact the regulation might have on the provision of first trimester abortion services in the state.

38. First, DHEC officials were not aware of any public health problem associated with facilities providing abortions in South Carolina and did not investigate whether there were any such public health problems prior to drafting the regulation. Indeed, it is undisputed that DHEC promulgated the regulation solely in response to the legislative directive contained within S.C. Code Ann. § 44-41-75.

39. After the legislation requiring licensure of abortion clinics was passed, Mr. Alan Samuels with DHEC was charged with the responsibility for supervising the drafting and promulgation of the regulation. Although Mr. Samuels has some experience in health care

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performing physician must possess, additional equipment which must be on hand, and additional medical tests which must be administered for second trimester abortions. Defendants have offered an additional "stipulation" regarding its provisions. Although not relevant to the challenge before this court, the section lends some support to the court's finding that second trimester abortions are more risky and raise different concerns than first trimester abortions.

administration, he has received no formal medical training or education. Upon completion of his college education, Mr. Samuels served in the United States Army for twenty-four years, where he served with the adjutant general corps and the medical services corps as a personnel officer and hospital inspector. After leaving military service, Mr. Samuels began employment with DHEC, where his duties consisted of inspecting various types of health care facilities for compliance with existing regulations. He was eventually promoted to the position of director of the DHEC Health Licensing Division, and has now retired.

40. Although Mr. Samuels provided some input and edits during the drafting process, he did not personally draft any portions of the regulation. Rather, he delegated the primary drafting responsibility to Mr. George Moore, who was the Director of Outpatient and Home Care within the Division of Health Licensing. Mr. Samuels admitted that he knew very little about abortion procedures or the differences between first trimester and second trimester abortions when the regulation was promulgated. His testimony also reveals that he personally conducted no meaningful study or research into the differences between a first and second trimester abortion, and conducted no meaningful inquiry into what regulatory requirements were appropriate for facilities performing only first trimester abortions.

41. Like Mr. Samuels, Mr. Moore has some education and experience with hospital administration, but has received no formal medical training or education. After receiving an undergraduate degree, Mr. Moore joined the United States Army where he served twenty-five years. He spent the early part of his service in the adjutant general corps performing general administrative duties, after which time he transferred to

the medical services corps where he performed administrative duties associated with health care facilities and hospitals. During his service, Mr. Moore received a masters degree in hospital administration. Upon his retirement from military service in 1988, Mr. Moore began employment with DHEC, inspecting hospitals and nursing homes for compliance with existing regulations. He was later promoted to Director of Outpatient and Home Care within the Division of Health Licensing, the position he held when Mr. Samuels asked him to assume primary responsibility for the drafting of the regulation. In preparation for drafting the regulation, however, Mr. Moore also took no meaningful steps to educate himself about first trimester abortions, how they differed from second trimester abortions, or what requirements would be appropriate for a facility which performed only first trimester abortions.

42. For assistance with Parts VII and VIII of the regulation (Fire Protection and Prevention/Design and Construction), Mr. Moore turned to Mr. William Lafferty, who was the Director of Health Facilities Construction with DHEC. Like Mr. Samuels and Mr. Moore, Mr. Lafferty has received no formal medical training or education. He testified that in drafting these portions of the regulations, he made no effort to determine whether the requirements were medically appropriate for facilities performing only first trimester abortions and that this was not his orientation. Mr. Lafferty also testified that he approached the design and construction requirements from the standpoint of new construction requirements and anticipated that existing facilities would be grandfathered. The decision to include a mandatory two-year compliance provision in that portion of the regulation was not made by Mr. Lafferty.

43. According to Mr. Moore, the preexisting South Carolina regulation governing second trimester abortions was utilized as a starting point for the new regulation, and many of the additional provisions of the new regulation were simply adopted or derived from DHEC regulations governing other types of health care facilities. They included regulations governing Ambulatory Surgical Centers, Renal Dialysis Facilities, Community Residential Care Facilities, Day Care Facilities for Adults, Outpatient Facilities for Chemically Dependent Persons, Habitation Centers for the Mentally Retarded, Residential Treatment Facilities for Children and Adolescents, Nursing Homes, and facilities providing home health care and hospice services. According to defendants, DHEC sought to standardize its regulations governing medical facilities and medical care so that the licensing requirements would have consistent wording, and to codify existing departmental practices.

44. According to the DHEC officials, this attempt to standardize its regulations and to codify existing practices included DHEC's desire to grant its inspectors the authority to copy medical records in all medical facilities. Mr. Moore testified that departmental practice currently allows the copying of medical records during a complaint investigation and that DHEC would maintain the confidentiality of the records. However, there is no provision in Regulation 61-12 which would mandate such confidentiality and defendants have pointed to no other state laws or regulations which would, in the court's opinion, adequately protect a patient's confidential medical records. In addition, the court notes that the DHEC regulation governing ambulatory surgical centers contains a specific provision protecting the

confidentiality of medical records. See S.C. Code Regs. 61-91, Section 1001.E (providing that records may only be removed from the premises by subpoena or court order).

45. Furthermore, defendants presented no evidence comparing the patient risks presented in other types of facilities regulated by DHEC with those presented in physicians' offices or clinics performing first trimester abortions, with the possible exception of ambulatory surgical centers. However, the medical evidence presented reveals, and there is little dispute, that the risks and potential complications of surgical procedures typically performed in ambulatory surgical centers are significantly higher than those associated with first trimester abortions.[8] Yet a comparison of the regulations reveals that in many ways Regulation 61-12 imposes requirements more stringent than those imposed upon ambulatory care centers. Furthermore, there is no evidence in the record as to how DHEC formulated the regulations applicable to ambulatory surgical centers, or whether they received substantial assistance from medical professionals during the drafting process. Accordingly, the mere fact that some of the requirements contained within Regulation 61-12 are similar to those contained within the ambulatory surgical center regulation is of little assistance to this

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[8] Indeed, the regulation itself recognizes this distinction. Under the regulation, licensed abortion clinics are restricted to performing abortions within 18 weeks lmp. Clinics performing abortions beyond 14 weeks lmp must meet the additional patient care requirements in Section 309 of the regulation (which requires additional physician qualifications, medical equipment, and mandatory laboratory tests). Abortions beyond 18 weeks lmp must be performed in a hospital, although a licensed ambulatory surgical center that is also licensed as an abortion clinic may perform abortions on patients up to 26 weeks lmp. See S.C. Code Regs. 61-12, Section 302.

court in determining whether they are appropriate requirements to impose upon a physician or clinic performing only first trimester abortions.

46. Although the DHEC officials testified that they primarily utilized existing South Carolina regulations as the basis for the challenged regulation, defendants have pointed to additional sources of information to defend the regulation. First, there is testimony that Mr. Moore obtained copies of abortion regulations from North Carolina and Tennessee. However, Mr. Moore did not speak with anyone in those states about the regulations or how they had affected maternal health and, in any event, the requirements of Regulation 61-12 exceed those contained in the regulations of these neighboring states. There is also testimony that Mr. Moore reviewed standards and guidelines issued by the Planned Parenthood Federation of America, Inc. ("Planned Parenthood"), the National Abortion Federation ("NAF"), and the American College of Obstetricians and Gynecologists ("ACOG"). However, with the exception of Planned Parenthood, which requires its affiliates to comply with its standards unless an exception is granted, the majority of the standards reviewed by Mr. Moore are not mandated standards of medical care. Rather, they are guidelines which must be accommodated to the needs of a particular facility and its patients through the exercise of physician judgment and discretion. Furthermore, a comparison of Regulation 61-12 with the standards and guidelines offered in support of the regulation reveals that DHEC in fact far exceeded even those guidelines.

47. According to witnesses presented by both sides of this controversy, ACOG is a well-respected, nationwide organization of obstetricians and gynecologists which serves to develop and further the standard of care in this

specialty. During the drafting process, the general counsel of ACOG wrote a letter to DHEC expressing concern that the requirements of the regulation would not enhance patient well-being or safety and offering DHEC the assistance of ACOG in the drafting of an appropriate regulation. The DHEC drafters declined ACOG's assistance.

48. After an initial draft of Regulation 61-12 was completed, Mr. Moore requested limited input and comments from two medical personnel associated with DHEC. The first, Richard Goodrich, M.D., is a licensed physician, board certified in obstetrics and gynecology, who practiced in Zanesville, Ohio until he retired. After his retirement, he moved to South Carolina and became a consultant with DHEC in the area of maternal and child health. During his medical practice, however, Dr. Goodrich performed only two abortions, both of which were due to medical complications. Furthermore, Dr. Goodrich was not asked to and did not draft any portion of Regulation 61-12. Rather, he was only asked to review discrete portions of the regulation dealing exclusively with medical events and medical testing, and he conducted no review of and provided no input on the majority of the regulatory requirements. While he is of the opinion that the portions of the regulation that he reviewed are appropriate medical standards of care, he testified that the same standards would be appropriate for physicians' offices in which comparable obstetrical and gynecological surgical procedures are performed. Dr. Goodrich further testified that he did not recommend the regulation's requirement of physician qualifications beyond state licensure, and acknowledged that he did not know how the required "training and experience" qualifications could be determined under the regulation. Dr. Goodrich also interpreted the regulation's

requirement that a registered nurse be "on duty" as requiring that a registered nurse have ultimate responsibility, and not that a registered nurse should or needs to be on the premises at all times. Dr. Goodrich further testified that, while he has no specific experience with medical abortions, it would not be his intent to cover the provision of medical abortions under the regulation. He acknowledged, however, that the regulation as drafted would in fact cover such abortions. Finally, Dr. Goodrich testified that he is aware of no existing problem with abortion providers in South Carolina and has no opinion as to how the cost and availability of abortions affect women's health issues.

49. Mr. Moore also sought some limited input from Robert Lawyer, R.N., who was Director of Nursing for DHEC. Mr. Lawyer received his bachelor of science degree in nursing while in the United States Army, and later received a masters degree in health services management and business administration. He has some experience with providing nursing care for first and second trimester abortions performed in a military hospital. After retiring from the Army in 1989, he began working with DHEC. He is currently nurse manager with the Division of Health Licensing, where his primary duty is the inspection of various health care facilities for compliance with existing regulations. He too was only asked by Mr. Moore and Mr. Samuels to review and provide input concerning discrete portions of the regulation, primarily those governing nursing care. Mr. Lawyer is of the opinion that, for first trimester abortions, a registered nurse should either personally monitor the patient or supervise all patient care, unless the physician is present in the facility and available to come to the recovery room if necessary. Unlike Dr. Goodrich, however, he interprets the

regulation as requiring the "on duty" registered nurse to be on the premises. In formulating his opinion, Mr. Lawyer did not conduct any research on abortion practices in South Carolina, nor did he consult with nursing professionals who specialize in abortion procedures. Mr. Lawyer testified that while he is aware that the regulation would apply to facilities performing only medical abortions, he has no knowledge of what nursing skills are required in the context of medical abortions or whether they would require a registered nurse as opposed to a licensed practical nurse.

50. With the exception of these limited consultations with medical personnel associated with DHEC, the drafters of Regulation 61-12 did not seek any input from medical professionals during the drafting process and rejected ACOG's offer of assistance. As some support for the text of the regulation, defendants contend that the drafters conducted a "mock inspection" of Planned Parenthood's facility in Columbia, South Carolina and determined that the facility met the great majority of the regulation's requirements. The evidence presented, however, reveals that the drafters simply toured the facility and, during one such visit, may have spoken briefly to a Planned Parenthood physician. There is no evidence that the physician was asked to comment upon the regulatory requirements or whether they were medically indicated for first trimester abortions, nor does the evidence support a finding that DHEC received any meaningful input from Planned Parenthood physicians prior to or during the early stages of the drafting process.[9]

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[9] In addition, DHEC places great reliance upon the fact that Planned Parenthood is not a plaintiff in this action. According to the testimony of a Planned Parenthood representative, Planned Parenthood did not participate in the lawsuit for political reasons, but agrees that the

51. After this initial drafting process was concluded, DHEC issued a proposed regulation and held public hearings as mandated by the APA. Some of the suggestions made during this public comment period resulted in changes to the regulation, including some suggestions made by Planned Parenthood and the plaintiffs in this case.

52. On January 23, 1996, DHEC submitted the regulation to the South Carolina Legislature for approval, as required by the APA. Because the legislature took no action on the regulation within 120 days after its submission, it became automatically effective upon publication in the State Register on June 28, 1996.

53. Plaintiffs filed this lawsuit the day before the regulation's publication date. As noted previously, this court enjoined its implementation on July 19, 1996 via a temporary restraining order, which the parties agreed to continue pending a determination on the merits of plaintiffs' claims.

F. Testimony of Local Providers of Surgical Care

54. At the trial, Dr. Terry Buffkin, Dr. Thomas Campbell, Dr. William Lynn, and Dr. Richard Manning testified concerning the regulation at issue and its probable effect on the health of women and the availability of abortions in South Carolina.

55. Dr. Terry Buffkin is board certified in obstetrics and gynecology, licensed to practice medicine in South

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regulation is largely unnecessary and, as a whole, unduly burdensome. The court finds the absence of Planned Parenthood as a plaintiff in this action to be irrelevant to the determination of the issues before it.

Carolina, a fellow in ACOG, a member of numerous state and local medical organizations, and has been granted admitting privileges at two local hospitals. He and his partner, Dr. Campbell, have been performing first trimester abortions at GWC since 1978.

56. Dr. Buffkin testified that first trimester suction curettage abortions can be safely performed in a physician's office, clinic, ambulatory surgical center or hospital. Ambulatory surgical centers, however, are typically used for more invasive type procedures (such as tubal ligations and laparoscopic procedures), and hospitals would be appropriate only if the patient has other significant medical problems which might complicate the procedure (such as heart disease). Dr. Buffkin also testified that medical abortions can be safely performed for ectopic pregnancies in a physician's office or clinic setting.

57. Dr. Buffkin testified that he is aware of no public health problem with the provision of abortion services in South Carolina and that he is aware of no physicians or others who are providing inadequate health care in regard to first trimester abortions in South Carolina.

58. Dr. Buffkin testified that GWC already complies with some, but not all, of the requirements of Regulation 61-12. For example, Dr. Buffkin testified that they do not perform all of the medical tests mandated by the regulation as a matter of course, but rather perform only those medical tests that are indicated based upon the patient's history, risk factors, and physical examination. He testified that the ACOG guidelines are not, and should not be, mandated standards of medical care, and that they can be varied from without compromising good patient care.

59. Dr. Buffkin testified that the regulation will not improve the health care of women seeking first trimester abortions in the state. He further testified that the regulation will directly increase the cost of abortion services to patients in South Carolina because it mandates the performance of unnecessary and expensive tests. It will also increase costs by imposing detailed administrative, structural, and other requirements which, although perhaps appropriate in an ambulatory surgical center or hospital environment, are not necessary in a small clinic or physician's office where the staff interacts daily. Dr. Buffkin also opined that the detailed requirements carry significant hidden costs in the nature of penalties and legal fees to challenge cited violations in the future. Finally, Dr. Buffkin is of the opinion that the increased cost of abortion services will result in a number of women either delaying the procedure or being unable to obtain the procedure, both of which increase the health risks to the pregnant woman.

60. Dr. Thomas Campbell is also a licensed physician in South Carolina, board certified in obstetrics and gynecology, and has been granted admitting privileges at several local hospitals. He is also of the opinion that Regulation 61-12 will increase the cost and decrease the availability of abortion services in South Carolina. Dr. Campbell testified that the detailed provisions of the regulation are unnecessary and inappropriate for a clinic performing first trimester abortions, and that they will not improve the health of women seeking abortions in South Carolina.

61. Dr. William Lynn is also licensed to practice medicine in South Carolina, is board certified in obstetrics and gynecology, and has been granted admitting privileges at a local hospital. He has been performing first

trimester abortions continuously since 1980. Dr. Lynn testified that he is aware of no public health problem associated with the provision of abortions in South Carolina. It is his opinion that the regulation will greatly increase the cost of abortion services in South Carolina, may make it impossible for some physicians to continue to offer abortion services, will not enhance women's health or increase the level of medical care in the community, and will make it more difficult for women to obtain reasonable abortion care in a safe setting. He further opines that the regulation is inappropriate for a first trimester abortion clinic and is instead more suited to a hospital environment. Dr. Lynn testified that the regulation mandates standards of care and costs which are contrary to the current trend of moving medical care away from hospitals and into outpatient facilities and physicians' offices to decrease costs.

62. Dr. Richard Manning is also board certified in obstetrics and gynecology, and is licensed to practice medicine in South Carolina and five other states. He currently serves as medical director of CWMC and performs first trimester abortions on a regular basis. He shares the opinion that the regulation will increase the cost of abortions and will not improve health care, and that the detailed regulations, while possibly appropriate for a large hospital, are unnecessary for a small clinic performing first trimester abortions where people work together and communicate daily.

63. In addition to the testimony of the plaintiff providers, plaintiffs presented expert testimony of a well-qualified general surgeon licensed to practice medicine in South Carolina. According to the testimony of this witness, licensed physicians currently perform a number of surgical procedures in their private offices --

particularly those which do not require the use of general anesthesia -- because it is significantly quicker, less expensive, and more comfortable for the patient. The surgeon's testimony, in conjunction with the other medical evidence presented by the parties, reveals that the risks and potential complications associated with surgeries typically performed in the office setting by general surgeons are substantially similar to those associated with first trimester abortions. Significantly, the general surgeon testified that physicians' offices in which such comparable procedures are performed, including his own, would not comply with a number of the requirements imposed by Regulation 61-12, yet would meet appropriate standards of surgical care.

64. Plaintiffs also presented the testimony of a clinical assistant professor of nursing at the University of South Carolina, who has observed and/or participated in a total of twenty-five to fifty abortions performed in the first and second trimesters of pregnancy, and who currently provides follow-up care to women who have received abortions. According to this witness, licensed practical nurses are competent to provide nursing care during the abortion and recovery period, and such nursing care is adequate to meet the needs of the patients. The witness was further of the opinion that requiring a registered nurse to supervise all nursing care in a facility performing only first trimester abortions is unnecessary if a physician is supervising care, and that it is permissible to allow a licensed practical nurse to observe the recovery of an abortion patient while the physician is in another room in the facility. In addition, the witness opined that, under current standards of practice, a registered nurse who is supervising nursing care in lieu of a physician would be unable to provide direct patient care.

G. Additional Expert Testimony Presented

65. At the trial, the parties presented conflicting testimony of independent experts on the medical appropriateness of Regulation 61-12 and whether it would further or harm maternal health in South Carolina. This testimony is summarized below.

1. David A. Grimes, M.D.

66. Plaintiffs called as an expert Dr. David A. Grimes. Dr. Grimes is a board certified physician in preventive medicine, with a specialty in public health, obstetrics and gynecology. He has over 25 years of experience with abortion procedures, as well as extensive experience in public health and abortion safety. He was asked to review the regulation by plaintiffs for the purposes of this case.

67. According to Dr. Grimes, ACOG and NAF publish guidelines and standards for abortion care to provide guidance to physicians in providing such care. They are not, however, a mandated standard of care. Rather physicians must be allowed to exercise their discretion in applying the guidance documents to meet the individual needs of their practices and patients.

68. Dr. Grimes also testified that it is not good medical practice to force costs upon patients which are not justified by the potential health benefits and that, in the private sector, this type of mandated medical care would not be tolerated by patients or, under managed care, by the insurance industry. Dr. Grimes testified that Regulation 61-12 will not further the health of women seeking abortions in South Carolina and, if enacted, will harm the health of women in South Carolina. It is his opinion that most of its requirements

are medically unnecessary and unduly burdensome to women and abortion providers.

69. By way of example, Dr. Grimes testified that the sections requiring written policies and procedures on patient rights, quality improvement and operating procedures are unnecessary for a physician's office or small clinic, although they may be appropriate for a hospital. Similarly, clinical staff meetings are appropriate for a hospital, but not a physician's office where the employees work together in a small environment. According to Dr. Grimes, the mandatory medical testing requirements are medically baseless and a misuse of public health resources, and that these are the types of medical care decisions which should be made by a physician in consultation with the patient based upon individual risk factors and needs. For example, a mandatory urine pregnancy test imposes additional costs, but is superfluous if the physician has already confirmed pregnancy through a blood test or ultrasound. And a urinalysis is not necessary in all cases, and is not required prior to surgery even in a hospital environment. Dr. Grimes is also of the opinion that the physical plant requirements are burdensome and will not result in the improved health and safety of women. While some may be appropriate to a hospital or facility which deals with open wounds, this is not the case with a first trimester abortion. In addition, Dr. Grimes is of the opinion that the copying of medical records is a violation of patient confidentiality. As he points out, the patient can give written consent for the release of medical records if the patient has a complaint.

2. Dr. Stanley K. Henshaw

70. Dr. Stanley K. Henshaw also testified via videotaped

deposition. Dr. Henshaw received a Ph.D in sociology from Columbia University and a bachelor's degree in physics from Harvard College. He is currently deputy director of research at the Alan Guttmacher Institute in New York, where he conducts studies relating to family planning and abortion services.

71. Dr. Henshaw testified that an increase in the price of abortion procedures prevents a number of women from obtaining abortions and causes other women to delay their abortions until further along into their pregnancies. Dr. Henshaw also testified that relatively small increases will have this effect, and that an increase of just $25 can be expected to prevent one or two out of every 100 low-income women seeking an abortion from being able to obtain one.

72. Dr. Henshaw also testified that a decrease in the number of abortion providers in South Carolina will result in a decrease in the number of women who are able to obtain an abortion in the state, and a corresponding increase in the number of women who must travel out-of-state to obtain the procedure. Such a need to travel will, in turn, reduce the ability to obtain an abortion or result in a delay in obtaining the abortion. And the need to travel carries its own costs, which will increase the overall cost of obtaining the abortion and compound the financial problem.

3. Charles J. Ward, M.D.

73. At the trial of this case, defendants called as an expert Dr. Charles J. Ward, who is also board certified in obstetrics and gynecology, and a fellow of ACOG and the American College of Surgeons. However, while Dr. Ward has attended to patients experiencing spontaneous and missed abortions (or miscarriages), he

has no experience in providing elective abortions and no particularized expertise in abortion practice or public health -- nor has he witnessed an intended abortion. He has also not performed any gynecological surgery for approximately four years.

74. Dr. Ward agrees that abortion is one of the safest surgical procedures performed in the United States, and is also of the opinion that the majority of physicians practice to an acceptable level of care. However, Dr. Ward opined that Regulation 61-12 will improve the safety and well-being of women seeking abortions in South Carolina. More specifically, Dr. Ward testified that Regulation 61-12 incorporates, for the most part, current national standards applicable to the performance of abortions, will impose no burden upon medical providers who perform abortions in South Carolina, and will not hinder the medical judgment of physicians or their discretion in the performance of the procedure. Dr. Ward believes that the regulation is not only consistent with good medical practice, but medically necessary to protect the health and safety of women seeking abortions.

75. However, Dr. Ward formulated no opinion on whether implementation of the regulation would affect the cost or availability of abortions in South Carolina. He conducted no analysis on whether the costs associated with regulatory compliance would pose a substantial obstacle to women seeking abortions or whether it would have the effect of harming women. Rather, Dr. Ward only opines that compliance with Regulation 61-12 will not impose a significant burden upon physicians who are already practicing to the standard of care reflected in the regulation. According to Dr. Ward, costs of providing medical care should not influence the provision of care and, in contrast to the testimony of

Dr. Grimes and the general surgeon, opined that "you do not weigh the dollar when you're practicing good medicine." Tr. at 1041.

H. Credibility of the Witnesses

76. Having observed the witnesses' demeanor and listened to their testimony, the court finds the testimony of Drs. Buffkin, Campbell, and Lynn to be credible based upon their extensive knowledge, training, and experience in providing first trimester abortions in South Carolina. Although they are owners of the abortion clinics challenging the regulation at issue, they are licensed to practice medicine by the State of South Carolina and are all board certified in obstetrics and gynecology. They have also been provided admitting privileges to hospitals in this state. Furthermore, they have been performing first trimester abortions in South Carolina on a regular basis for many years and there is no credible evidence that they have been providing services which do not meet acceptable standards of medical care. Nor is there any evidence that their patients have experienced significant complications from the abortion procedures.

77. Dr. Manning, whose testimony was submitted by deposition, is also licensed to practice medicine in this state and is board certified in obstetrics and gynecology. He has been performing first trimester abortions in this state for a number of years with no evidence of significant complications or an inadequate standard of care. His opinions are consistent with those of Drs. Buffkin, Campbell, and Lynn, and the court find his testimony to be credible as well.

78. The court also finds Dr. Grimes' testimony to be credible. Dr. Grimes has over 25 years of experience

with abortion procedures, as well as specialized knowledge in abortion safety and public health. He too has provided testimony consistent with that of the other physicians who testified.

79. The court finds the testimony of the general surgeon to be particularly credible. Although he does not perform abortion procedures, he is a general surgeon licensed to practice medicine in this state and has provided valuable testimony about the current acceptable practice of performing surgery in an office setting and the general safety and tolerable risks associated with that practice.

80. Having observed the demeanor and testimony of Dr. Ward, the court discounts substantial portions of the evidence he submitted. Like Dr. Grimes, Dr. Ward was not involved in drafting Regulation 61-12 and was hired to review the regulation solely as an expert witness in this case. However, although Dr. Ward is board certified in obstetrics and gynecology, he has not performed any gynecological surgery in several years, has no experience in providing elective first trimester abortions, and has no particularized expertise in abortion practice or public health. In recent years, Dr. Ward has been hired primarily by parties in litigation as an expert witness in medical malpractice cases. He has also worked in academia, but has had limited involvement in the hands-on practice of medicine. Thus, Dr. Ward's expertise in areas determinative to this case is limited. In addition, Dr. Ward has formulated no opinion as to the regulation's probable effect on the cost or availability of abortions in South Carolina -- factors which this court is required to consider in determining the constitutionality of the regulation. Furthermore, Dr. Ward appears to substantiate his opinion through a belief that the cost of

medical services is irrelevant to the provision of quality medical care -- an opinion which the court finds is contrary to the current trends and realities in the practice of medicine.

81. With regard to the DHEC medical witnesses, Dr. Goodrich and Mr. Lawyer, their testimony was presented to the court via depositions and an assessment of their credibility is more difficult. Having reviewed the deposition excerpts provided, however, the court notes that their experience with the provision of abortion services has been limited at best or occurred many years ago. For these reasons, the court discounts to a degree the value of their testimony.

I. Costs to Comply with the Regulation

82. In compiling anticipated costs to comply with Regulation 61-12, plaintiffs independently reviewed the regulation and calculated the costs of bringing their respective clinics into compliance. In the case of the design and construction requirements, plaintiffs retained an outside construction specialist to inspect their facilities and provide a renovation estimate to comply. Plaintiffs presented evidence that CWMC would require renovations costing approximately $27,235, that PSMC would require renovations costing approximately $2,700, that Dr. Lynn's Beaufort office would need renovations costing approximately $12,256, and that GWC would need renovations costing approximately $3,700. In addition, plaintiffs presented detailed cost estimates to comply with the regulation's additional requirements -- such as the costs associated with developing and implementing the numerous programs and policies, conducting the administrative reviews, ensuring the required staff training, and hiring additional staff. In each case, the

costs were broken down into one-time costs, annual costs, and per-procedure costs. These figures were, in turn, provided to a certified public accountant who calculated the average "cost per-procedure" impact.

83. Defendants contend that the plaintiffs' cost figures are "grossly inflated," although not intentionally so. For example, they have variously contended as to certain items that plaintiffs misread the regulatory requirements or misinterpreted them, or that they have inaccurately estimated or improperly included costs associated with professional and staff time which will be taken by their compliance efforts. They have also taken issue with plaintiffs' inclusion of the cost associated with hiring a registered nurse to supervise nursing care, contending that the clinics can replace an existing licensed practical nurse and allow the registered nurse to both supervise and provide hands-on care. As to Dr. Lynn, defendants contend that he has demonstrated poor business practices which are the cause of his much higher compliance costs. Thus, defendants have taken plaintiffs' estimates, adjusted them for the errors they perceive, and provided the court with an alternative cost increase figure.

84. Nevertheless, it is readily apparent that Regulation 61-12 will impose substantial start-up costs upon abortion providers in this state, and substantial annual costs to maintain compliance. As with any other business, these costs will be passed along to the patients in the form of increases in the price of receiving abortion services. And, of course, additional direct costs will be imposed upon plaintiffs through the performance of the mandatory medical testing.

85. Currently, a first trimester suction curettage abortion costs between $325 and $480, depending upon the

gestational age, the type of sedation or anesthesia needed, and the medical testing indicated. According to the evidence presented, Regulation 61-12 will raise the cost of each abortion service in South Carolina in the following ranges:[10]

> For CWMC, the cost will increase $36.48 to $75.03;
>
> For PSMC, the cost will increase $93.09 to $170.39;
>
> For Dr. Lynn's Beaufort practice, the cost will increase $115.67 to $367.50;
>
> For GWC, the cost will increase $22.68 to 32.39.

86. At trial, the parties entered into the following stipulations of fact concerning the cost of complying with certain specific provisions of the regulations, as follows:

> When directly billing physicians, laboratories in South Carolina generally charge between $20.00 and $40.00 per sample to perform a combined test for chlamydia and gonorrhea.
>
> When directly billing physicians, laboratories in South Carolina generally charge between $17 and $30 per sample to test for the Du variant.

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[10] The lowest figure represents defendants' revision of plaintiffs' estimates. The highest figure represents plaintiffs' estimate. Neither, however, takes into account the standard 15% profit factor which plaintiffs' accountant testified would be appropriate.

When directly billing physicians, laboratories in South Carolina charge between $7 and $20 per sample to perform a test for syphilis and between $10 and $22 to perform a test from a pap smear.

The range in charges for these tests varies due to a number of factors, including the number of samples that the physician submits to the laboratory for such tests. Discounts are generally offered when more tests are submitted.

A set of surgical instruments for performing the suction curettage abortion costs approximately $200.

87. Having reviewed all of the evidence presented, the court agrees with plaintiffs, and finds as a fact that compliance with Regulation 61-12 will be a costly endeavor which will result in a substantial rise in the cost of abortion services. The court also finds that the substantial alterations that Dr. Lynn must undertake in his practice, and the resulting extraordinary per procedure cost (even by defendants' estimate) will likely force him to cease performing abortions in his Beaufort office and, thereby, eliminate entirely the availability of abortions in this area of the state.[11]

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[11] Defendants have sought to minimize the impact from the closure of Dr. Lynn's Beaufort office by pointing to Planned Parenthood's plans to open a clinic there in the future. However, as of the trial in this case, Planned Parenthood had not raised sufficient funds to open a clinic in the area. Furthermore, under the current plans, Planned Parenthood would not provide abortions up to 13.9 weeks (as Dr. Lynn does), and would offer the service for fewer hours and days. Simply stated, Planned Parenthood's potential to fill the void left by Dr. Lynn in this area of the state is speculative at best.

88. The court also finds as a fact, based upon the medical and other testimony presented, that the increased cost of providing abortions resulting from the regulation will prevent a significant number of women from obtaining an abortion or, at a minimum, delay them from obtaining the abortion, both of which carry increased risks to the health of women.

J. Additional Findings

89. Based upon all of the reliable and credible evidence in this case, the court finds that the first trimester suction curettage abortion is one of the safest surgical procedures that can be performed. The procedure lasts approximately two to five minutes and has a relatively low overall complication rate. Suction curettage abortions can be, and are currently being, safely performed in physicians' offices and outpatient clinics, except where the patient has particular medical conditions that would require the procedure to be performed in an ambulatory surgical center or hospital. Medical abortions are also quick medical procedures that can be safely performed in a physician's office or outpatient clinic.

90. Physicians' offices and clinics that provide less than five first trimester abortions per month perform identical procedures to those which provide five or more first trimester abortions per month, and the risk to the patient undergoing the abortion procedure is identical. Offices and clinics that provide less than five first trimester abortions per month, however, are for inexplicable reasons exempt from any regulation or licensure by DHEC, and the patients seeking an abortion there are free to decide in consultation with their physicians what tests are appropriate.

91. First trimester suction curettage abortions are comparable in terms of risks, duration and invasiveness to a variety of obstetrical and gynecological surgical procedures which are frequently performed in physicians' offices in South Carolina. These would include suction curettage procedures performed on women who have experienced an incomplete spontaneous abortion, dilation and curettage procedures, endometriai biopsies, hysteroscopies, and insertion of intrauterine devices for birth control. Physicians' offices performing such procedures are, however, also not subject to DHEC regulation or oversight. Nor are their patients subjected to mandatory tests.

92. First trimester suction curettage abortions are also comparable in terms of risks, duration and invasiveness to a variety of non-obstetrical/gynecological surgical procedures that are frequently performed in physicians' offices in South Carolina. These would include the removal of subcutaneous lipomas and cysts, minor breast biopsies, and the removal of implanted ports and catheters which have been inserted into large veins in the neck and collarbone region for use in administering chemotherapy and dialysis. These physicians' offices are likewise not subject to DHEC regulation or oversight, nor are their patients subjected to mandatory tests.

93. South Carolina is not currently experiencing a public health problem related to the provision of first trimester abortions by licensed physicians, nor was the state experiencing such a problem when Regulation 61-12 was promulgated. There is no evidence that the plaintiffs or any other abortion providers in South Carolina are providing inadequate care to women seeking abortions or that the rate of complications from

abortions performed in South Carolina is greater than the national average. On the contrary, it appears that South Carolina has experienced a similar, if not lower, average complication rate. All of the witnesses with knowledge of the issue testified that they are aware of no serious medical complications resulting from the performance of a first trimester abortion in this state, and it is uncontested that the challenged regulation was drafted by DHEC in response to the state legislative directive and not in response to a public health problem in this state.

94. Although the principal draftsmen of Regulation 61-12 have some expertise in hospital and health care administration, they have no training or education in the provision of hands-on medical care and little knowledge of the medical needs of women seeking first trimester abortions in South Carolina. They engaged in virtually no research, investigation or other efforts to determine what types of requirements would be necessary or advisable for the procedure, or what types of requirements would further or hinder the state's interest in maternal health. Nor did DHEC officials possess or seek information concerning the present safety of first trimester abortions or the relative risks associated with the procedure.

95. Despite their admitted lack of medical knowledge in general and of abortion procedures in particular, the drafters of Regulation 61-12 also sought only minimal input and assistance from knowledgeable medical experts during the drafting process, choosing to rely solely upon the limited review and advice of Dr. Goodrich and Mr. Lawyer as to discrete portions of the regulation. Furthermore, DHEC either rejected or ignored an offer by ACOG to assist in the drafting process. While DHEC was under no legal obligation to

consult with ACOG or to accept their assistance during the drafting process, ACOG is unanimously considered by the witnesses in this case -- including those presented by defendants -- to be a well-respected medical organization dedicated to improving the standard of health care in the field of obstetrics and gynecology. DHEC's rejection of their assistance further demonstrates their lack of interest in ensuring that the regulation actually met the proffered goal of promoting maternal health and is consistent with the testimony of the DHEC witnesses that such a goal was not their primary motivation during the drafting process.

96. Although it is uncontroverted that first trimester abortions are significantly less risky to the health of women than second trimester abortions, an existing South Carolina regulation governing second trimester abortions was utilized as a starting point for the new regulation. With the exception of Section 309 of Regulation 61-12, the drafters drew no distinction between first and second trimester abortions in the text of the regulation. In addition, the drafters admitted that virtually no such distinctions were considered during the drafting process.

97. Instead of attempting to tailor Regulation 61-12 to the particularized medical needs of women seeking first trimester abortion services in South Carolina, DHEC's orientation during the drafting process was to standardize its health care and facility regulations and to codify existing departmental practices. To the extent this was done, it was done without any meaningful inquiry or assessment as to whether the requirements would further the state's interest in maternal health and without assessing whether first trimester abortions were comparable to the procedures performed in the other facilities regulated by DHEC. In particular, while

DHEC has pointed to its regulation governing ambulatory surgical centers as support for Regulation 61-12, it is undisputed that offices and clinics that provide first trimester abortions provide services that are significantly less risky, invasive and lengthy than the services offered in ambulatory surgical centers. Yet many of the requirements of Regulation 61-12 are as stringent, or in some respects more stringent, that those imposed upon ambulatory surgical centers.

98. The Planned Parenthood, NAF, and ACOG standards and guidelines relied upon by DHEC are recommendations by the respective organizations and are not fairly characterized as mandated standards of care which can or should be imposed upon licensed physicians as regulatory requirements. Rather, they are guidelines which should be followed with due regard for the medieal judgment of the treating physicians and the special needs of the patients they serve. Even if some of the existing guidelines could, in isolation, be appropriate matters for regulation, the current Regulation 61-12 imposes requirements which greatly exceed them.

99. In imposing the detailed requirements of Regulation 61-12, the DHEC drafters also failed to take any meaningful steps to evaluate the costs of compliance or its impact upon the availability of abortion services in South Carolina. Based upon the evidence presented, the court finds that Regulation 61-12 will significantly increase the cost of abortion services in South Carolina. This increase in the cost of abortion services will delay a significant number of women from obtaining the procedure and, in some cases, result in their inability to obtain the procedure. As a pregnancy advances, the medical risks associated with abortion increase, and a full term pregnancy and childbirth is much more risky to the physical health of a woman than a first trimester

abortion.

100. Most likely as a result of these deficiencies in the drafting process, Regulation 61-12 consists of a myriad of detailed and costly provisions that were neither designed to further the health of women seeking first trimester abortions in South Carolina nor likely to accomplish this goal. Indeed, by imposing additional costs and impediments to women seeking abortions, the regulation may have the unintended effect of increasing the risk of adverse health conditions. The infirmities in the regulation are pervasive and a comprehensive recitation of the unnecessary and/or unduly burdensome provisions is neither possible nor necessary. A few examples should suffice:

a. Part I -- The first, and most immediate, problem with Regulation 61-12 is found in its definitions of an abortion and of an abortion clinic, which in turn determines its scope. The applicability of the regulation is not limited to suction curettage abortions, or even to surgical abortions -- nor is it limited to clinics operated by hospitals or non-physicians. And unlike the ambulatory surgical center regulation, there is no exemption for privately operated physicians' practices. Thus, the regulation will be immediately applicable to any facility (other than a hospital) in which any second trimester and/or five or more first trimester abortions are performed per month -- thereby encompassing within it a private physician's office. An abortion is defined as "[t]he use an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus," S.C. Code Regs. 61-12, Section 101.A., and would,

therefore, include the medical abortions currently being used to terminate ectopic pregnancies. DHEC's own consultant, Dr. Goodrich, did not realize the definition was so all encompassing, and does not attempt to assert that the stringent provisions of Regulation 61-12 would be appropriate for a facility or physician performing only medical abortions. Furthermore, by directing that the regulation be applied to any facility performing five or more first trimester abortions per month, DHEC has ensured its applicability to all abortion and family planning clinics, as well as to all physicians who choose to regularly perform (i.e. more than five times per month) first trimester abortions in their private practice -- yet it in no way regulates or limits the discretion of a licensed physician who performs the identical abortion procedures in his office on a less frequent basis.

b. Part II -- Administration and Management. This portion of Regulation 61-12 is permeated with unnecessary requirements governing physician qualifications, staffing, and staff training. By way of example, the regulation requires physicians and clinics to hire a registered nurse to supervise all nursing care in the facility regardless of the fact that a licensed physician is present in the facility to supervise all medical care, including nursing care. The reliable and credible evidence presented reveals that it is within accepted medical practice, both within the abortion context and in physicians' offices performing comparable surgical procedures, for a physician to hire licensed practical nurses (who command a lower salary than registered nurses) so long as they act under the supervision of the attending physician. Clearly, a licensed physician is capable of supervising nursing care in the room in which he is performing the procedure. And defendants have offered no persuasive

reason why a physician cannot supervise the nursing care of patients during the recovery process simply because the physician may be another room for a brief period of time. Indeed, DHEC's own medical consultant, Dr. Goodrich, opined that a registered nurse need not be on the premises to supervise care -- only that the nurse have overall supervisory duties.

Similarly, the court finds inadequate justification for requiring physicians who perform first trimester abortions to have admitting privileges at a local hospital or a written transfer agreement with a physician who has such privileges. The state has a legitimate interest in ensuring that all outpatient surgery patients have access to appropriate emergency care when needed. And all of the abortion providers involved in this case, for example, have such privileges or have verbal transfer agreements to ensure that their patients will receive appropriate emergency care should the need arise. Plaintiffs contend that many physicians would be resistant to entering a written transfer agreement with abortion providers because, under other portions of the regulation, the agreement would be subject to copying and potential public dissemination. The court finds this to be a reasonable concern, given the controversial nature of abortions and the absence of any evidence that verbal transfer agreements have not in the past, or would not in the future, adequately meet the state's interest in this regard.

Other provisions of the regulation would seem to appear reasonable at first blush, but fail upon closer examination. For example, a requirement that all health care personnel receive tuberculin skin testing would appear to be very reasonable from a public health standpoint. However, DHEC has not required such testing of all health care personnel -- choosing instead

to impose the costly testing only upon clinics and physicians' offices which perform abortions on a regular basis. Defendants have offered no justification for arbitrarily requiring this testing of all abortion care workers, but not all other health care workers. Nor does it appear that they could do so. Similarly, Regulation 61-12's requirement that all allied health care personnel in abortion clinics receive CPR training would appear reasonable, but it too is a requirement imposed solely upon abortion providers who perform, according to all of the witnesses, one of the safest surgical procedures that is performed in this country. Furthermore, the credible evidence reveals that while it is prudent for all health care facilities and physicians' offices to have an employee trained in CPR available at all times, the regulation's requirement that all abortion clinic employees be trained is clearly unnecessary given the extremely low probability that a patient undergoing a first trimester abortion procedure will need such drastic treatment. And in keeping with the regulation's pervasive tendency to "overdo" every requirement, Sections 206-208 of the regulation do no more that require facilities and physicians to comply with laws they are already obligated to obey, on pain of additional penalties.

c. Part III. Patient Care. The level of policies and procedures required by this Part, as well as the extensive inservice training requirements and other policies required in Part II of the regulation, are also costly endeavors unsubstantiated by a medical need. As succinctly testified to by many of the medical experts in this case, such requirements may be appropriate for large medical care facilities with large staffs that do not interact on a daily basis. However, Regulation 61-12 arbitrarily imposes it upon every clinic and every physician's office which performs five

or more first trimester abortions per month -- regardless of the number of staff or hours of operation.

Furthermore, this portion of Regulation 61-12 unnecessarily restricts the medical discretion and judgment of treating physicians who are already licensed by this state and subject to oversight by the State Board of Medical Examiners. By mandating the presence of certain medical equipment and the performance of certain medical testing, Regulation 61-12 constitutes a regulatory intrusion into the physician-patient relationship and directly imposes costs upon patients which are not medically indicated a majority of the time -- simply because the patient has chosen to undergo an elective abortion. For example, there is no reason to charge a patient seeking an abortion for a urine pregnancy test when the physician has already confirmed the pregnancy by other means (such as by a blood test or ultrasound). Nor has a rational explanation been offered for the regulation's mandate that every woman undergo (and pay for) testing for certain sexually transmitted diseases (but not others), without regard to whether such tests are medically indicated and indeed even when the physician determines that they are not, simply because the woman has chosen to obtain a first trimester abortion from a physician who performs them on a regular basis. Section 307's requirement that abortion providers have "consulting" arrangements with various specialists before they can obtain a license to operate is also medically unnecessary and unduly burdensome. The court has been made aware of no convincing reason why licensed physicians are not capable of exercising appropriate discretion in recognizing and acting upon the medical needs of their patients in this regard.

The regulation also inexplicably imposes

requirements concerning access to emergency drugs which are not imposed upon any other physicians and which, instead of improving health care, may well harm health care by imposing obstacles to accessing the drugs by the providers themselves. The equipment and supplies required by the regulation will also increase the costs of providing abortions in the state, and require equipment not necessary for the safe performance of the first trimester abortion procedure.

d. Part IV. Medical Records and Reports. This portion of the regulation also suffers from serious infirmities. For example, the apparent requirement that a woman seeking an abortion provide the name of her spouse in addition to an emergency contact is a medically and legally unnecessary requirement which imposes a substantial obstacle in the path of a woman who, for personal reasons, may wish not to disclose this information.

e. Parts V, VI, and VII of Regulation 61-12 suffer from similar infirmities. While a number of the provisions in these Parts would appear reasonable, they do not hold up under closer scrutiny. First, the provisions for "Functional Safety and Maintenance," "Infection Control and Sanitation," and "Fire Protection and Prevention" are not imposed upon physicians' offices where less than five first trimester abortions are performed per month, or where comparable surgical procedures are performed regardless of the frequency. For example, initially it would appear that regulations in the area of infection control and sanitation would be quite reasonable. However, they would be no more or less necessary in a first trimester abortion clinic than in a physician's office performing fewer than five procedures per month or in a physician's office performing comparable procedures.

In addition, the section is often duplicative of OSHA requirements, and admittedly requires autoclave testing with a frequency that is far greater than what is medically appropriate. Other of the provisions invite arbitrary enforcement (such as generically requiring that a facility be kept "free of hazards"), or impose requirements (such as the posting of a disaster preparedness plan and conducting quarterly fire drills) which may be appropriate for a large clinic or hospital, but not a small physician's office. In summary, these parts, and indeed the entire regulation, is pervaded with unnecessary regulatory requirements which are selectively, and without medical justification, imposed upon physicians and clinics solely because they perform first trimester abortions on a regular basis.

f. Part VIII, entitled "Design and Construction," suffers from similar problems. It imposes extensive and detailed design and construction requirements for abortion facilities which far exceed building code requirements applicable to other physicians' offices, including those that perform identical and comparable procedures. At trial, defendants presented the testimony of a well-qualified architect, who endorsed a majority of the design and construction requirements as being appropriate recommendations for a state of the art medical facility. This court has no doubt that the architect's designs are excellent ones. However, the reliable and credible medical evidence presented at trial leaves little doubt that these extensive requirements, while perhaps appropriate for a hospital or large ambulatory surgical center, are not justified by expected medical benefits to the women undergoing the relatively safe, first trimester suction curettage abortion in a small physician's office or clinic. Indeed, a number of the requirements are not purported to be

ones advancing the interest of improving the health care for abortion patients, but rather are life safety issues in the event of a disaster, fire or other event requiring evacuation. Furthermore, business occupancies which meet the design and construction requirements of standard building codes sufficiently meet these life safety concerns, and have not been required to "upgrade" to state of the art design and construction standards.

The additional requirements, which are advanced as unique to the medical field, simply find no justification in medical necessity. For example, there is no evidence supporting a need for physicians to install additional bathroom equipment and emergency call buttons or that they have a recovery area separate from the procedure area. Nor is there any evidence to indicate that physicians should be required to widen their doors and corridors to a width sufficient to accommodate both an ambulance stretcher and a person walking alongside to perform cardiopulmonary resuscitation, particularly given the unanimous testimony that a first trimester abortion is a relatively safe procedure with infrequent complications. Indeed, there is no evidence that this need has ever arisen from the performance of a first trimester abortion in this state (or elsewhere). And, of course, physicians performing surgical procedures of comparable invasiveness and risk are not required to renovate their offices to meet a similar requirement. Perhaps least defensible of all is the fact that abortion facilities are required to fully comply with the design and construction requirements within two years from licensure, while facilities admittedly performing much riskier procedures (including ambulatory surgical centers) are grandfathered.

g. Part IX. Prerequisites for Initial Licensure. This

portion suffers from similar problems as the design and construction portion of the regulation, requiring numerous certifications and laboratory test results concerning various parts of the facility (such as the carpets and draperies) without any evidence that the requirements will further the goal of protecting women's health in South Carolina.

h. Finally, Part X of the regulation, in conjunction with Section 103.C., grants to DHEC unfettered power to "manage[ ]" abortion providers "in accordance with the best practices as interpreted by the Department," S.C. Code Regs. 61-12, Part X, and to cite providers with a Class III violation and penalty if DHEC observes a condition deemed to be "against the best practices as interpreted by the Department," S.C. Code Regs. 61-12, Section 103.C. Simply put, in addition to the burdens imposed by Regulation 61-12's comprehensive, detailed provisions, the regulation imposes upon abortion providers the additional burden of determining and complying with standards or practices not specified in the regulation, but which DHEC may in the future find to be "best" for an abortion clinic.

II. CONCLUSIONS OF LAW

A. Due Process and the Right to Privacy

1. Introduction

1. "Abortion is recognized as a fundamental right protected by the Due Process Clause of the Fourteenth Amendment." Manning v. Hunt, 119 F.3d 254, 259

(4th Cir. 1997).[12] This has been the case since Roe v. Wade, when the United States Supreme Court held that the "right of privacy ... founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action ... is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." 410 U.S. 113, 153 (1973). Under Roe, state laws and regulations restricting the right could only be allowed if they were supported by a compelling state interest and were narrowly drawn to express the interest. See id. at 155.

2. The Supreme Court in Roe, however, recognized that the right to choose "is not unqualified," id. at 154, and that it must be considered against important and legitimate state interests in preserving and protecting the health of the pregnant woman and in protecting the potentiality of human life, see id. at 154, 162. To assist in weighing the competing interests of the woman and the state, the Roe Court adopted a "trimester framework," designed to delineate when the state's interest became sufficiently compelling to justify the state's limitation of or infringement upon the right. Specifically, the state's interest in the health of the pregnant woman was considered to be compelling at the end of the first trimester, after which time the state could "regulate the abortion procedure to the extent that the regulation reasonably relat[ed] to the preservation and protection of maternal health." Id. at 163. Prior to that point in time, however, the abortion decision was to be left to the physician's medical judgment, in consultation with the woman. See id. After viability, the state's interest in potential life became compelling,

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[12] The Fourteenth Amendment states in pertinent part that "... nor shall any State deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV.

and the state was free to regulate and even prohibit the abortion procedure except when an abortion was necessary to preserve the life or health of the mother. See id. at 163-64.

3. In the years following Roe, application of its trimester framework resulted in almost no regulation being permitted during the first trimester of pregnancy. See Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 872 (1992). But because a woman's constitutional liberty to have some freedom to terminate her pregnancy was not unlimited, "[t]he extent to which the legislatures of the States might act to outweigh the interests of the woman in choosing to terminate her pregnancy was the subject of debate both in Roe itself and in decisions following it." Id. at 853.

4. In Casey, a majority of the United States Supreme Court reaffirmed the "essential holding" of Roe, maintaining that a woman's right to choose an abortion is a fundamental one protected by the Due Process Clause of the United States Constitution, but one which must be weighed against the state's legitimate interests in preserving and protecting the health of women seeking abortions and in the potentiality of human life. See Casey, 505 U.S. at 846. A plurality of the Court, however, rejected the rigid trimester framework of Roe. Although maintaining that "the line should be drawn at viability, so that before [viability] the woman has a right to choose to terminate her pregnancy," Casey, 505 U.S. at 870, the Casey plurality sought to reaffirm, and afford more weight, to the state's "legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child," id. at 846. Specifically, the plurality observed that:

> [t]hat portion of the decision in Roe ha[d] been given too little acknowledgment and implementation by the Court in its subsequent cases. Those cases decided that any regulation touching upon the abortion decision must survive strict scrutiny, to be sustained only if drawn in narrow terms to further a compelling state interest.

Id. at 871.

5. Noting that "not every law which makes a right more difficult to exercise is, ipso facto, an infringement of that right, id. at 873, the Casey plurality articulated an 'undue burden' standard as 'the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty,'" Casey, 505 U.S. at 876, thereby seeking to modify the standard for evaluating state regulations which impact the abortion decision prior to viability, including those within the first trimester of pregnancy. After viability, the State could continue to "regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." Id. at 879 (internal quotation marks omitted).

6. As noted by the Fourth Circuit, "[t]he difficulty presented to lower federal courts following Casey lies in the fact that only three justices -- Justices O'Connor, Kennedy, and Souter -- have specifically adopted this undue burden standard." Manning, 119 F.3d at 260. The Fourth Circuit, however, "deem[ed] it proper to follow the trend clearly set by other courts" and to apply the "undue burden" test to challenges brought against state laws regulating abortion. Id. at 261.

7. A question remains, however, as to what plaintiffs must show to successfully mount a facial challenge to an abortion regulation. In United States v. Salerno, 481 U.S. 739 (1987), the Supreme Court held that a party asserting a facial challenge to a legislative Act is required to "establish that no set of circumstances exists under which the Act would be valid," id. at 745. The fact that the Act "might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid." Id. Since Casey was decided, however, the circuits have been divided on the issue of whether the Supreme Court sub silentio overruled Salerno's "no set of circumstances" test for facial challenges to state laws regulating abortion, requiring instead that the challenger only show "that in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Casey, 505 U.S. at 895; see Manning, 119 F.3d at 268-69, n. 4 (discussing division of authority on the issue); Planned Parenthood of the Blue Ridge v. Camblos, 155 F.3d 352, 358-59 n. 1 (4th Cir. 1998) (en banc) (same); id. at 381 n. 14 (same); id. at 389 n. 2 (Michael, J. concurring) (concluding Salerno no longer applies in this context).

8. In granting plaintiffs' motion for a temporary restraining order on July 19, 1996, this court ruled that it intended to follow those courts which had held that Casey implicitly superseded the Salerno "no set of circumstances" test for challenges to abortion regulations. Since that time, however, the Fourth Circuit has touched upon the conflicting views on this issue, albeit not directly deciding it. In Manning, the court applied the Salerno standard of review to an abortion statute, but plaintiffs did not challenge its applicability. See Manning, 119 F.3d at 268-69. In

dicta, however, the three-member panel suggested that the court would nonetheless apply the Salerno standard until the Supreme Court explicitly overruled it, stating that:

> [i]t is not the province of the court of appeals to predict how the Supreme Court will ultimately rule on an issue. Casey does not specifically overrule Salerno. At the moment, the most that can be said is that three Justices have indicated a desire to do so. Until the Supreme Court specifically does so, though, this Court is bound to apply the Salerno standard as it has been repeatedly applied in the context of other abortion regulations reviewed by the Supreme Court.

Id. at 269 n. 4; see also Camblos, 155 F.3d at 381 n. 14 (noting the Manning dicta, but not deciding the question); id. 155 F.3d at 389 n. 2 (Michael, J., concurring) (asserting that the Casey undue burden test must be applied to facial challenges to abortion restrictions).

9. As a result of the uncertainty which remains concerning the appropriate standard to be applied in this case, the court will review Regulation 61-12 under both the Casey and Salerno standards. In addition, the court is mindful that, when presented with a challenge to the constitutionality of a state statute, it should construe the law, if possible, to avoid a finding of unconstitutionality. See Ohio v. Akron Reprod. Health Ctr., 497 U.S. 502, 514 (1990); Camblos, 155 F.3d at 383. However, "'federal courts are without power to adopt a narrowing construction of a state statute [to avoid constitutional difficulties] unless such a construction is reasonable and readily apparent.'"

Virginia Soc'y for Human Life, Inc. v. Caldwell, 152 F.3d 268, 270 (4th Cir. 1998) (quoting Boos v. Barry, 485 U.S. 312, 330-31 (1988)) (emphasis in original).

2. The Undue Burden Test

10. Under Casey, the State of South Carolina may regulate the performance of abortions, even those during the first trimester of pregnancy, in order to further legitimate state interests in the health of the mother and the life of the fetus. However, the woman maintains her fundamental right "to choose to have an abortion before viability and to obtain it without undue interference from the State," Casey, 505 U.S. at 846, (emphasis added) and "the State's interests [prior to viability] are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure," id. (emphasis added).

11. In Casey, the Supreme Court was presented with constitutional challenges to various provisions in a Pennsylvania statute governing informed consent, parental consent, recordkeeping and reporting requirements, and a medical emergency exception. Thus, the plurality opinion focused on the state's legitimate interest in the potentiality of human life -- holding that to promote this "profound interest in potential life, throughout pregnancy the State may take measures to ensure that the woman's choice is informed, and [that] measures designed to advance this interest will not be invalidated so long as their purpose is to persuade the woman to choose childbirth over abortion" and they do not impose "an undue burden on the right." Id. at 878.

12. Nevertheless, the Casey plurality also provided

guidance by addressing the state's concomitant, and equally legitimate, interest in preserving and protecting the health of women seeking abortion services -- of particular relevance to the challenge in this case. Specifically, the Casey plurality held that:

> As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion. Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right.

Id. at 879.

13. The types of burdens that may be imposed by state regulation are varied in nature, but clearly include financial burdens which restrict or prohibit the exercise of the right. As noted by the Casey plurality:

> [n]umerous forms of state regulation might have the incidental effect of increasing the cost or deceasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it. Only where the state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.

Id. at 874 (emphasis added).

14. Furthermore, "[n]ot all burdens on the right to decide whether to terminate a pregnancy will be undue." Id. at 876.

> A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.

Id. at 877 (emphasis added).

15. Although the Casey court was not presented with regulations similar to those at issue in this case, previous Supreme Court cases provide additional guidance as to the appropriate level of regulations designed to protect the health of women seeking abortions. First, in Roe, the Supreme Court recognized that:

> abortion in early pregnancy, that is, prior to the end of the first trimester, although not without its risk, is now relatively safe. Mortality rates for women undergoing early abortions, where the procedure is legal, appear

> to be as low as or lower than the rates for normal childbirth. Consequently, any interest of the State in protecting the woman from an inherently hazardous procedure, except when it would be equally dangerous for her to forego it, has largely disappeared. Of course, important state interests in the areas of health and medical standards do remain. The State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that insure maximum safety for the patient.

Roe, 410 U.S. at 149-150 (emphasis added). In addressing permissible state regulation to serve the legitimate goal of maternal health after the first trimester of pregnancy, the Roe court held that:

> a State may regulate the abortion procedure to the extent that the regulation reasonably relates to the preservation and protection of maternal health. Examples of permissible state regulation in this area are requirements as to the qualifications of the person who is to perform the abortion; as to the licensure of that person; as to the facility in which the procedure is to be performed, that is, whether it must be a hospital or may be a clinic or some other place of less-than-hospital status; as to the licensing of the facility; and the like.

Id. at 163 (emphasis added). Applying these principles in the companion case of Doe v. Bolton, 410 U.S. 179 (1973), the Court simultaneously invalidated a Georgia law requiring that all first trimester abortions be performed in a licensed hospital where the state failed to show that only the hospital environment could ensure

the quality of the operation and the protection of the patients. Id. at 195.

16. Later, in City of Akron v. Akron Ctr. for Reprod. Health, Inc., 462 U.S. 416 (1983), the Supreme Court was presented with a challenge to an Ohio ordinance which, among other things, required all second trimester abortions to be performed in a hospital. Reaffirming the prohibition against over-regulation of a relatively safe surgical procedure, the Court held that:

> [t]he State's discretion to regulate on th[e] basis [of maternal health] does not ... permit it to adopt abortion regulations that depart from accepted medical practice.... If a State requires licensing or undertakes to regulate the performance of abortions during this period, the health standards adopted must be "legitimately related to the objective the State seeks to accomplish."

Id. at 431 (quoting Doe, 410 U.S. at 195). The Court then invalidated the ordinance, holding that it "imposed a heavy, and unnecessary, burden on women's access to a relatively inexpensive, otherwise accessible, and safe abortion procedure." Id. at 438.[13]

17. Circuit courts of appeal called upon to address the propriety of comprehensive health regulations, after Roe but before Casey, have similarly invalidated them

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[13] The Supreme Court in Casey overruled those parts of Akron which were "inconsistent with Roe's statement that the State has a legitimate interest in promoting the life or potential life of the unborn," see Casey, 505 U.S. at 870, but reaffirmed the essential holding of Roe. Thus, the Akron decision continues to inform this court as to the propriety of regulations purportedly enacted to further the state's interest in maternal health.

when there was an insufficient nexus between the nature of the medical procedure and the extent of the regulation. See e.g., Birth Control Ctrs., Inc. v. Reizen, 743 F.2d 352, 364-65 (6th Cir. 1984) (invalidating detailed, specific regulatory criteria governing the physical layout of abortion facilities, staffing requirements, and equipment requirements); Ragsdale v. Turnock, 841 F.2d 1358 (7th Cir. 1988) (invalidating portions of a similar licensure regulation which mandated, among other things, detailed physical plant requirements, policies and procedures, and staff training requirements.)

18. The plurality opinion in Casey rejected the trimester framework of Roe in order to afford greater recognition to the states' legitimate interests in maternal health and potential life during the first trimester of pregnancy. Thus, Casey may fairly be said to now allow states to regulate in areas previously thought to be improper, i.e. medical facilities performing first trimester abortions. However, there is no indication that the Supreme Court would now approve state regulation which substantially disregards the training, discretion and judgment of the licensed physician performing the relatively safe, first trimester suction curettage abortion. On the contrary, the Casey Court repeatedly reaffirmed the essential holding of Roe and specifically counsels this court to examine purported health regulations for medical necessity. Casey, 505 U.S. at 879. In addition, Roe's discussion regarding the relative health care needs of abortion patients is consistent with the medical evidence presented in this case -- indeed, it can be fairly concluded that advances in medical care have rendered the first trimester abortion an even safer procedure today. At a minimum, Roe and Casey counsel this court to be particularly mindful of the relative safety and low risks associated with first trimester abortions in

evaluating whether the requirement of Regulation 61-12 are medically necessary, and in evaluating whether they reasonably relate to the stated goal of protecting and preserving the health of women seeking such abortions in the State of South Carolina. See Casey, 505 U.S. at 878.

19. Guided by these precedents, the court concludes that the State of South Carolina has a legitimate interest from the outset of pregnancy in protecting the health of women seeking abortions, and that this interest is sufficiently important to allow the State to regulate abortion providers, including providers which limit their services to abortions during the first trimester of pregnancy. See Casey, 505 U.S. at 876. Furthermore, this interest would allow the state to regulate, within the boundaries of Casey and its predecessors, such matters as the qualifications of the person performing the procedure, the facilities in which abortions are performed, and the availability of medical care after the procedure and in the event of an emergency. See Roe, 410 U.S. at 149-50, 163.

20. However, just as the woman's fundamental right to obtain an abortion is not limitless, the state's power to regulate in these areas is not unfettered. To withstand constitutional scrutiny, Regulation 61-12 must first be designed to further the state's legitimate goal of protecting and preserving the health of women seeking abortions and must be reasonably related to that goal. See Casey, 505 U.S. at 878; Roe, 410 U.S. at 163. Casey and its predecessors inform us that health regulations which are unnecessary, not reasonably related to maternal health, or which depart from accepted medical practice, cannot withstand constitutional scrutiny and must be invalidated. See Casey, 505 U.S. at 878; Akron, 462 U.S. at 431; Roe,

410 U.S. at 163. Furthermore, even if Regulation 61-12 furthers the interest of protecting and preserving the health of women seeking abortions, the regulation cannot stand if it imposes an undue burden on a woman's fundamental right to obtain an abortion, see Casey, 505 U.S. at 877-78, as a regulation which has "the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." Id. at 877.

a. S.C. Code Regs. 61-12 was not designed to and does not further the state's legitimate interest in maternal health.

21. Having carefully reviewed the evidence presented in this case, the court concludes that Regulation 61-12 is unconstitutional under the Due Process Clause of the United States Constitution because it was not designed to and does not further the state's legitimate interest in maternal health.

22. Although the DHEC officials responsible for drafting and finalizing Regulation 61-12 may have set out to promulgate some portions of the regulation to serve the state's interest in promoting and preserving the health of women seeking abortions, they have failed in that endeavor. Simply put, they have gone too far -- imposing costly requirements that are at best medically unnecessary and at worst contrary to accepted medical practice.

23. As an initial premise, the court agrees with plaintiffs' contention that defendants may not rewrite the regulation to correct its constitutional infirmities. Defendants may not offer such "stipulations" without plaintiffs' consent, and they are more properly

considered to be concessions by defendants that there are defects in the sections referenced. Nor can the court consider them to be a reasonable interpretation of the language of the referenced sections. The statutory sections which are relied upon to ensure confidentiality are contained within a separate chapter of Title 44 of the South Carolina Code of Laws. Even if they were applicable to abortion facilities, the language is insufficient to ensure the confidentiality of patients seeking abortion services. The remainder of the proffered "stipulations" are clearly intended to rewrite the text of the sections at issue.

24. Furthermore, the court concludes that the infirmities in the regulation go far beyond those sections which defendants seek to correct through their stipulations. Rather, the evidence in this case reveals, and the court concludes, that the very drafting and promulgation process surrounding Regulation 61-12 ensured its failure to serve the permissible constitutional goal of preserving and protecting the health of women seeking abortions.

25. The evidence is undisputed that a first trimester abortion is a relatively safe medical procedure with minor risks to the health of the woman. However, the DHEC officials charged with the task of drafting and promulgating Regulation 61-12, while possessing some expertise in the area of hospital administration, had no formal medical education or training, sought no significant input or assistance from knowledgeable medical professionals, rejected assistance from a reputable medical organization, and conducted no meaningful inquiry into what standards of care should be mandated in view of the relatively minor risk level associated with a first trimester abortion procedure. Instead, the DHEC officials have conceded that the

regulation was drafted primarily from the prior state regulation governing second trimester abortion facilities and from other DHEC regulations governing other types of health care facilities and procedures, in an attempt to "standardize" its health care regulations.[14] Thus, it is hardly surprising that the regulation imposes numerous requirements which are medically unnecessary for the safe performance of first trimester abortions.

26. The medical evidence exposing the constitutional infirmities is overwhelming. Plaintiffs have presented this court with extensive testimony and evidence proving that first trimester abortions can be and are being safety performed in existing physicians' offices and clinics, and that South Carolina is not currently experiencing any public health problem with the performance of first trimester abortions. Regulation 61-12, however, imposes extensive, unduly restrictive, and costly requirements upon physicians and clinics which, in some cases, conflict with or go beyond accepted medical practice for first- trimester abortions

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[14] DHEC may have a legitimate interest in standardizing its health care regulations and codifying existing departmental practices. However, this court is not called upon to decide whether this interest has been appropriately served. DHEC did not adopt new regulations applicable to all outpatient care facilities, including abortion clinics. Nor did DHEC adopt new regulations which would be applicable to all physicians performing surgical procedures in their offices or even to all physicians performing abortions in their practices. Instead, DHEC promulgated extensive medical care regulations aimed solely at abortion providers who regularly perform abortion procedures, without meaningful input from medical professionals and without regard to the safety needs and risks specific to the abortion procedure. And many of the requirements contained within Regulation 61-12 go beyond even those requirements imposed upon, for example, ambulatory surgical centers which clearly perform surgical procedures which carry an increased risk to the health and safety of its patients.

and which collectively impose substantial costs and other burdens upon the providers and the patients. Every part of the regulation, and nearly every section, contains requirements which are unnecessary to the provision of quality health care to women seeking abortions or are not designed, by DHEC's own admission, to further that interest. And the regulation as a whole imposes burdensome requirements that far exceed those applicable to physicians' offices which perform procedures which are substantially similar, and in some cases identical, to a first trimester suction curettage abortion.

27. The specific requirements of Regulation 61-12 which find no basis in medical necessity are too numerous to mention, and the extensive nature of the regulation and its obviously unnecessary detail cannot be fully appreciated without a complete reading of its text. The unnecessary provisions permeate virtually every section, and to identify them individually and recount the evidence demonstrating their excessiveness could double the length of this order. If called for, this court would not hesitate to accept the task; but after spending months reviewing all aspects of this case, the court cannot help but conclude that the constitutional problems with this regulation are so numerous and pervasive that their elimination would leave a hollow regulation. A few examples should suffice.[15]

28. As an initial matter, Regulation 61-12 is riddled with unnecessary requirements that place excessive burdens on physicians' offices and clinics solely because five or more first trimester abortions are performed there per month. In isolation many of the provisions would sound like good ideas; however, the testimony from the

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[15] Additional examples can be found in the court's findings of facts.

medical experts whom this court found credible reveals that many of these individual provisions contain requirements that should not be mandated in every case as this regulation would dictate. For example, testing a person for particular sexually transmitted diseases might sound like a good idea. But where there are no symptoms or other accepted medical reasons or risk factors to justify such a test, there is no reason to test a woman for them just because she seeks an abortion. Yet this, as an example, is what several of the provisions do -- they require the physicians affected by the regulation to abdicate their own medical judgment and to test every pregnant woman who wants an abortion for selected sexually transmitted diseases, regardless of the medical justification.[16] Similarly, the regulation requires the administration of a urine pregnancy test to all women, regardless of whether the physician has confirmed the pregnancy through other means.

29. Not only does the regulation mandate medical tests that the testimony shows to be uncalled for, but it also places administrative burdens on the clinics which are clearly inappropriate to medical offices of such small sizes as these offices and clinics. For example, DHEC has mandated -- without regard to the number of staff or size of the clinic -- the development of extensive policies and procedures, frequent staff meetings, formal inservice training and required staff certifications, and medical testing of employees which, while probably

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[16] Defendants apparently seek to have this court conclude that the selected diseases are much more prevalent in women seeking abortions or that abortion clinics present a public health problem in this regard. Even assuming such a finding would support the regulatory requirement, defendants have simply presented insufficient evidence to support such a finding.

appropriate for a hospital or large outpatient surgical center, are unnecessary in a small physician's office or clinic. With regard to the design and construction requirements, the refusal to grandfather existing clinics is unprecedented and no explanation has been given as to why existing abortion clinics are compelled to be in full compliance within two years, while other regulated health care facilities (including ambulatory surgical centers which admittedly perform more risky and invasive surgical procedures) are subjected to less stringent design and construction regulations and are permitted to perform surgery in their existing facilities until they choose to undergo substantial renovations. See, e.g., S.C. Code Regs. 61-91, Section 2001-2005 & 2106. On top of this, DHEC does not show how the extensive renovations required will further the health of women seeking abortions in South Carolina -- and no explanation is offered as to why all of these requirements are so much greater for these clinics than they are for other physicians' offices performing the same type of procedures.

30. In addition, the regulation, and in particular those portions pertaining to patient care, seeks to walk the licensed physician through the abortion procedure and recovery period with minimal if any regard for the fact that the physician is already required to have obtained a license to practice medicine from the State Board of Medical Examiners. It regulates the procedure from the content of the initial medical record through discharge of the last patient, and everything in between. By requiring such things as the medication to be kept and the tests which must be administered, the regulation strikes at the heart of the physician-patient relationship and ignores the physician's training and experience -- including the professional requirement that the physician assess each patient individually and exercise

discretion in order to serve the best interests of the patient. Similarly, no acceptable explanation has been provided as to why only a registered nurse, as opposed to a licensed physician, can supervise nursing care in the facility, and the credible medical evidence before the court indicates that this requirement is also unnecessary.

31. Despite the fact that there is no evidence of any abortion providers in the state rendering unsanitary or otherwise inadequate care, or that the Board of Medical Examiners is not able to discipline its own,[17] many of the other provisions of Regulation 61-12 border on the absurd. For example, the regulation requires that the entire facility "be kept ... free from odors" and that all outside areas "be kept free of rubbish, grass, and weeds that may serve ... as a haven for insects, rodents and other pests." S.C. Code Regs. 61-12, Sections 604 & 606. And, despite the fact that the existing level of detail would seem to defy continuous compliance by even the best of facilities, DHEC has granted itself authority to impose penalties for any condition which, while not mandated or prohibited by the regulation, DHEC deems to be "against the best practices" as later

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[17] Defendants have sought to defend the comprehensive nature of some of the regulatory requirements on the basis that some abortion clinics are owned and operated by non-licensed third parties who, unlike South Carolina physicians, require such detailed direction in the proper provision of medical care. As a general premise, the court agrees that some additional or different regulations may be appropriately applied to such facilities. However, the court cannot render findings and conclusions as to the appropriate level of such regulation because DHEC did not draw any such distinction in drafting the regulation at issue. Indeed, unlike the DHEC regulation for ambulatory surgical centers which exempts private physicians performing surgical procedures in their offices, DHEC made no attempt to distinguish or exempt from the requirements licensed physicians, such as Drs. Buffkin, Campbell, and Lynn, who perform abortions in their private practices.

defined by the department. S.C. Code Regs. 61-12, Section 103.C & Part X. By attempting to regulate such "common sense" items in minute detail, the regulation subjects physicians to unnecessary uncertainty in the operation of their practices and invites arbitrary enforcement.

32. While this court recognizes that some of the provisions of Regulation 61-12 are contained in other DHEC regulations governing other health care facilities, Regulation 61-12, unlike the other regulations, is directed to and impacts upon a medical procedure which has been afforded constitutional protection. And the court cannot ignore that abortion, unlike other types of surgical procedures, is the subject of much controversy, debate, and protest in this country. It is not sufficient simply to argue that because some of the provisions apply to other types of medical facilities and procedures, they are properly applied to first trimester abortions. Regulation 61-12 must be subjected to closer scrutiny, and a showing made that its provisions are, as an initial matter, rationally and legitimately related to the state's interest in preserving and protecting maternal health and that they will likely serve this goal. No such showing has been made in this case. On the contrary, DHEC took no meaningful steps to ensure that the provisions of S.C. Regs. 61-12 were designed to promote maternal health in the context of abortion care or to ensure that its provisions rested upon a reasonable medical basis. No doubt as a result of this uninformed endeavor, the regulation fails to serve the state's legitimate interest in preserving and protecting the health of women seeking first trimester abortions in this state and cannot be enforced on this basis alone. See Casey, 505 U.S. at 877-78.

33. Finally, in addition to the evidence that Regulation 61-

12 will not serve the goal of preserving and protecting the health of women, plaintiffs have presented persuasive evidence that the regulation will have the opposite effect. Specifically, because the regulation will result in a substantial increase in the cost of obtaining an abortion in South Carolina, a significant number of women will be forced to either delay having an abortion, or forego having one altogether, which will serve to increase health risks and diminish the safety of women seeking abortions in South Carolina.

b. S.C. Code Regs. 61-12 has the effect of imposing an undue burden on the woman's right to obtain an abortion

34. It is true, as defendants contend, that all state regulations impose some costs upon consumers and that all burdens on a woman's right to obtain an abortion will not be undue. However, states may not impose regulations, even those which result in minor costs, which serve no legitimate state interest and which are in conflict with the standards imposed by current medical practice. Given the lack of evidence that the regulation will operate to improve the health care currently being received in this state, and the substantial evidence that it may well have the opposite effect, the court concludes for the reasons discussed throughout this order that Regulation 61-12 must be invalidated. In addition, however, the regulation fails because it places a substantial obstacle in the path of women seeking first trimester abortions and, thereby, imposes an undue burden on the woman's fundamental right to choose to undergo the procedure. See Casey, 505 U.S. at 877-78. Thus, even were the court to assume that Regulation 61-12 could further the state's legitimate interest in protecting maternal health, it must still be found unconstitutional. Id.

35. Currently, a first trimester abortion costs between $325 and $480, depending upon the gestational age and the type of sedation or anesthesia given to the patient. The evidence in this case is that Regulation 61-12 will have the effect of increasing the cost of obtaining an abortion, at a minimum, between $30.00 and $75.00. In one area of the state, it will result in an increase of between $100 and $300, or result in the elimination of services altogether.

36. A significant increase in the cost of providing or obtaining an abortion alone can constitute a substantial obstacle to a woman seeking an abortion. See e.g., Casey, 505 U.S. at 901. By causing delays in the woman's financial ability to obtain an abortion, the regulation will cause the woman to undergo abortion later in the pregnancy, or forego the procedure altogether, both of which result in a higher cost and higher medical risk for the woman. The decreased availability of abortions due to closure of an abortion clinic also constitutes a substantial obstacle to women seeking abortions. And increasing the distance a woman has to travel to obtain an abortion increases the costs for the woman, again resulting in delay or the inability to obtain an abortion.

37. Less tangible burdens are also imposed by the regulation. For example, the regulation grants DHEC inspectors the right to inspect abortion clinics at will and without limitation -- and such inspections can be initiated by anonymous complaints. During any such inspection, the inspectors are also granted the right to copy confidential patient records. Although defendants contend that the records would be kept confidential according to DHEC's internal "policy," the regulation ensures no such protection. Indeed, according to the evidence presented, DHEC would still retain the

discretion to utilize such records in proceedings to enforce the regulation. This lack of sufficient confidentiality is further compounded by the fact that the regulation requires patients to disclose information, such as their husband's name, which is not necessary for the provision of safe medical care and which the patient may, for a number of reasons, prefer not to disclose. And the regulation requires the clinic to conduct follow-up reviews to include, in some cases, obtaining input from the patient's family members. Thus, the regulation not only raises the monetary cost of abortion services. It threatens patient confidentiality, grants DHEC inspectors unlimited discretion to inspect abortion facilities, allows anonymous third parties to lodge complaints to prompt such investigations, and results in an unnecessary intrusion into the patient's relationship with her physician and her family members. Thus, recognizing the fundamental nature of the right at issue and its controversial nature, the court concludes that the regulation imposes significant additional, and unnecessary, burdens upon patients seeking abortion services in the state.

3. Facial Invalidity of the Regulation

38. The court now turns to the issue of whether Regulation 61-12 is facially invalid, and the accompanying issue of the test to be applied.

39. First, for all of the reasons set forth in this order, this court concludes that "in a large fraction of cases in which [the regulation] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." Casey, 505 U.S. at 895. However, it equally fails Salerno's "no set of circumstances" test, which would require plaintiffs "to show that under no set of circumstances can the [regulation] be applied in a

manner which is not an undue burden on [a woman's] right to obtain an abortion." Manning, 119 F.3d at 269. In applying the Salerno test, this court must determine whether the regulation "can be construed in such a manner that [it] can be applied to a set of individuals without infringing upon constitutionally protected rights." Rust v. Sullivan, 500 U.S. 173, 183, (1991). And the court may not invalidate the regulation "based upon a worst-case analysis that may never occur." Ohio v. Akron Reprod. Health Ctr., 497 U.S. at 514.

40. The detailed requirements of Regulation 61-12 apply to every physician's office or other medical facility in which five or more first trimester abortions are performed per month, and to every woman who chooses to have the procedure performed in such a facility. Given the unduly detailed and restrictive requirements imposed by the regulation, and the lack of a sufficient nexus between these requirements and the stated goal of protecting and preserving maternal health, the court concludes that the regulation cannot be applied in a manner which is not an undue burden on the fundamental right to obtain an abortion. Although certain discrete portions of the regulation afford discretion in the manner of enforcement, the instant case simply does not present a regulatory requirement which, when presented in the "worst case" scenario, only operates in the "rare case" to present an undue burden. Id. The vast majority of Regulation 61-12's provisions are specific and detailed -- and once effective, would immediately require all abortion providers, including those already safely administering the procedure, to apply for and obtain a license to operate. Such licensure is, in turn, predicated upon immediate compliance with all of the detailed requirements of the regulation (with the exception of the design and construction standards which must be

met within two years), and the passing of a pre-licensure inspection. Thus, all affected abortion providers and their patients will, by the explicit terms of the regulation, be forced to immediately face the burdens and incur the additional costs imposed by the regulation.

41. Furthermore, it is undisputed that the regulation will impose burdens upon women seeking first trimester abortions and that it will increase the cost of a first trimester abortion. Although defendants contest that these burdens are "undue," the overwhelming and credible evidence reveals that the regulation is medically unnecessary and that its costs and other burdens, which the court concludes are indeed undue, are not justified by the stated interest in protecting the health of the women undergoing the procedure. The regulation was admittedly not designed solely to serve this interest, and it unsurprisingly will not do so.

B. EQUAL PROTECTION

42. The court now turns to plaintiffs' contention that S.C. Code Regs. 61-12 violates the Equal Protection Clause of the United States Constitution.

43. The Equal Protection Clause "commands that no State shall 'deny to any person within its jurisdiction the equal protection of the laws,' which is essentially a direction that all persons similarly situated should be treated alike." City of Cleburne v. Cleburne Living Ctr. Inc., 473 U.S. 432 (1985) (quoting Plyler v. Doe, 457 U.S. 202, 216 (1982)). However, the Equal Protection Clause does not prohibit all forms of discrimination among persons. Because "most legislation classifies for one purpose or another, with resulting disadvantage to various groups or persons," Romer v. Evans, 517

U.S. 620, 631 (1996), the general rule is that a classification will be upheld "so long as it bears a rational relation to some legitimate end," id. If, however, the legislation burdens a fundamental right or targets a suspect class, it will only be upheld if it is narrowly tailored to serve a compelling state interest. See Cleburne, 473 U.S. at 440, 105 S.Ct. 3249; see also Plyler v. Moore, 100 F.3d 365, 373 (4th Cir. 1996).

44. In enacting S.C. Code Ann. § 44-41-75, the South Carolina legislature directed DHEC to promulgate regulations for facilities in which five or more first trimester abortions are performed per month. In response, DHEC promulgated Regulation 61-12, which imposes upon the selected group stringent and costly requirements for licensure which far exceed the requirements imposed by the State of South Carolina upon other licensed physicians who perform comparable, and in some cases identical, surgical procedures in their offices. In order to obtain and maintain their license, the physicians and clinics subject to the regulation must, among other things, immediately comply with its extensive physical plant, staffing, equipment, and recordkeeping requirements, and acquiesce in DHEC's extensive limitation of their professional discretion. However, licensed physicians who choose to limit their abortion practice to the more occasional case or who choose not to perform abortions, are free to perform the identical or virtually identical procedures in their offices. They need not obtain or pay for any license for their offices or clinics, are subject only to the requirements and standards of the South Carolina Board of Medical Examiners, and may remain comfortable in the knowledge that their patients' medical records and medical care will remain confidential. Nor need they subject their patients, even those obtaining first trimester abortions, to medical

testing which they deem unnecessary or which their patients choose to decline.

45. The initial question presented is what level of scrutiny should be applied to the classification at issue. Plaintiffs urge this court to apply strict or heightened scrutiny because the classification penalizes the exercise of a fundamental right or, at a minimum, targets a suspect or quasi-suspect class. Defendants, on the other hand, contend that physicians do not constitute a suspect class for equal protection purposes and do not have a fundamental right to perform abortions. Accordingly, defendants argue that this court should apply the rational basis test.

46. Courts addressing the constitutionality of similar types of health care regulations have reached various conclusions under different tests. The most analogous to this case is Friendship Med. Ctr., Ltd. v. Chicago Bd. of Health, 505 F.2d 1141 (7th Cir. 1974), cited by plaintiffs in this case. In Friendship, the Seventh Circuit invalidated abortion service regulations promulgated by the board of health which sought to regulate such things as the design of the medical facility, the type of medical staff and its training, the maintenance of equipment, supplies, and medications, the content of medical records, and the types of medical tests which must be administered to abortion patients. Applying strict scrutiny, the court invalidated the regulation on both due process and equal protection grounds, because fundamental rights were involved. With regard to the equal protection analysis, the court held as follows:

> Given the Supreme Court's acceptance of the medical fact that the mortality rate of women receiving legal abortions is "as low as or

> lower than the rates for normal childbirth," there would seem to be little justification for more extensive governmental regulations, purportedly based on health considerations, for one procedure than the other.
>
> The Chicago Board of Health's Rules on Abortion Services regulate comprehensively physicians who perform abortions, while at the same time leaving other medical procedures, often much more complex and dangerous in terms of the patient's health, up to the good judgment of the physician.

Id. at 1152 (quoting Roe, 410 U.S. at 149) (internal citations omitted). Because defendants had offered no sufficiently compelling reason to justify the difference in treatment, the court invalidated the regulations. It had previously noted, however, that "on the record before th[e] court there is no basis for determining whether the regulations are even reasonably related to a valid state concern." Id. at 1150.

47. The Sixth Circuit has also been called upon to address such comprehensive health regulations. First, in Mahoning Women's Ctr. v. Hunter, 610 F.2d 456 (6th Cir. 1979), aff'g. 444 F. Supp. 12 (N.D. Ohio 1977), vacated on other grounds, 447 U.S. 918 (1980), the court affirmed the district court's decision to invalidate, under the strict scrutiny test, a city ordinance imposing costly medical and building code requirements on first trimester abortion clinics, while leaving unregulated the performance of other medical and surgical procedures. The district court had concluded that the ordinance impermissibly regulated only physicians who performed abortions, "while leaving other comparable medical procedures to the discretion of the attending

physician." Mahoning, 444 F. Supp. at 17. The Sixth Circuit subsequently issued its decision in Birth Control Ctrs., Inc. v. Reizen, 743 F.2d 352 (6th Cir. 1984), cited by defendants in this case. Reizen involved a Michigan licensing scheme which required all freestanding surgical outpatient facilities ("FSOFs") to comply with staffing, structural, equipment, counseling, consent, and recordkeeping requirements in order to obtain a license to operate. Because the licensing scheme applied to abortion clinics, albeit not exclusively, four abortion clinics challenged the scheme on equal protection grounds because it exempted private physicians' offices where abortions were performed. The court affirmed the district court's application of the rational basis test as the appropriate standard of review, because the "differentiation between FSOFs and physicians' private offices did not involve any suspect class nor implicate any fundamental right." Id. at 358 (footnote omitted). In particular, the court held that "[n]o suspect classification [was] involved ... since the State ha[d] chosen to regulate all FSOFs, not just abortion clinics," Reizen, 743 F.2d at 358, and distinguished its earlier ruling in the Mahoning case, see id. at 358 n. 4.

48. Finally, in Women's Health Ctr. of West County, Inc. v. Webster, 871 F.2d 1377 (8th Cir. 1989), the Eighth Circuit upheld an abortion regulation which required emergency back-up care against an equal protection challenge, applying the rational basis test. The court noted that, although the regulation applied only to abortion providers, the state already required such back-up care for all patients undergoing any outpatient surgery. Thus, the regulation was a reasonable means of ensuring the health of women seeking abortions and did not impose a special requirement upon abortion providers. See id. at 1381.

49. With these precedents in mind, and having reviewed the regulation at issue and the evidence presented, the court concludes that Regulation 61-12 violates the Equal Protection Clause of the United States Constitution.

50. First, it has been established since Roe that a woman's decision to terminate her pregnancy prior to viability involves the exercise of a fundamental constitutional right. See Roe, 410 U.S. at 155. Regulation 61-12 applies only to abortion providers and directly impacts the exercise of a fundamental right. Furthermore, South Carolina imposes no similar requirements upon physicians or clinics performing comparable procedures. Thus, the court finds it to be most analogous to the licensing scheme invalidated in Friendship and concludes that it must survive strict scrutiny analysis. See Friendship, 505 F.2d at 1152.

51. While the health and safety of women seeking abortion services in the state is a compelling state interest, it is no more or less compelling that the state's interest in ensuring the health and safety of all citizens seeking medical care from its licensed physicians. And for all the reasons previously discussed in this order, the court concludes that Regulation 61-12 clearly fails because it is not narrowly tailored to serve this compelling state interest.

52. Nevertheless, even were the court to conclude that Regulation 61-12 neither creates a suspect class nor burdens a fundamental right, the regulation must be invalidated under the more deferential rational basis review because the evidence and proffered justifications reveal that Regulation 61-12 is not rationally related to the stated legitimate purpose.

53. Although the most lenient of the tests which can be

applied to a classification, the rational basis test is not a directive to uphold state regulation simply because the state proffers a legitimate or even laudable goal. "[E]ven in the ordinary equal protection case calling for th[is] most deferential of standards," the court must find "the relation between the classification adopted and the object to be attained." Romer, 517 U.S. at 632.

> The search for the link between classification and objective gives substance to the Equal Protection Clause; it provides guidance and discipline for the legislature, which is entitled to know what sorts of laws it can pass; and it marks the limits of our own authority.

Id. "By requiring that the classification bear a rational relationship to an independent and legitimate legislative end, [the court] ensure[s] that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." Romer, 517 U.S. at 633. Furthermore, even if the disadvantaged group does not rise to the level of a "suspect" class entitled to the application of a strict scrutiny analysis, the court must not be blind to the fact that a law or regulation which disadvantages a politically unpopular group "raise[s] the inevitable inference that the disadvantage imposed is born of animosity toward the class of persons affected." Id. at 634. " '[I]f the constitutional conception of 'equal protection of the laws' means anything, it must at the very least mean that a bare ... desire to harm a politically unpopular group cannot constitute a legitimate governmental interest.'" Id. at 634 (quoting Dep't of Agric. v. Moreno, 413 U.S. 528, 534 (1973)).

54. The court now turns to defendants' proffered justifications for Regulation 61-12. First, defendants

contend that the regulation does not violate the Equal Protection Clause because the South Carolina legislature directed DHEC to promulgate a regulation for abortion clinics performing five or more first trimester abortions per month and because, in South Carolina, physicians' offices are otherwise regulated by the State Board of Medical Examiners and not by DHEC. The court rejects this argument.

55. The manner in which South Carolina chooses to regulate their licensed physicians cannot serve as a justification for treating a select group of physicians and their patients differently or to otherwise contravene equal protection rights. Stated otherwise, the state obviously cannot legitimize an otherwise violative classification simply by assigning regulatory authority over the burdened class to a different state agency.

56. Furthermore, while the legislature directed DHEC to regulate abortion facilities which perform five or more first trimester abortions per month, while leaving other licensed physicians under the exclusive supervision of the Board of Medical Examiners, it is undisputed that DHEC retained the discretion to refrain from treating comparable facilities and procedures differently. For example, DHEC could have treated abortion facilities like other physicians' offices and clinics by promulgating regulations consistent with what is already required in physicians' offices by other laws and accepted standards. As to the physical plant requirements of Regulation 61-12, DHEC could have adopted regulations requiring the facility to meet all applicable building codes. As to staff qualifications and medical records, DHEC could have required the supervising physician to hire staff and maintain medical records that, in his or her professional discretion, would appropriately provide for the needs and rights of the

patients. And for assistance in this area, DHEC could have sought input from the Board of Medical Examiners and/or from licensed gynecologists, as well as other physicians, who perform such procedures in an office setting. With regard to needs unique to the abortion procedure, DHEC could have treated abortion providers differently from other physicians' offices and clinics, but only based upon actual differences between those facilities.

57. Defendants only additional argument is that Regulation 61-12 does not violate the Equal Protection Clause because its provisions are rationally related to the legitimate state interest of protecting the health and welfare of women seeking abortions in the state. Defendants' argument appears to be two-fold. First, defendants contend that abortion providers and the abortion procedure have been traditionally placed in a special classification because the abortion decision implicates constitutional concerns and carries emotional ramifications, which set it apart from similar medical procedures. Second, defendants contend that, because abortions are invasive procedures with potentially serious complications, the state has a legitimate interest in promulgating uniform regulations and minimum standards for their performance within the state. Without such regulation, defendants contend, out-of-state abortion providers will be encouraged to come across the borders of South Carolina and perform large numbers of abortions within the state.

58. The first contention can be summarily rejected. Abortions and abortion providers have unquestionably been afforded special protection under the Constitution. This fact, however, does not allow for more stringent regulation; on the contrary, it supports application of a more stringent constitutional review. And while

defendants are correct that the abortion procedure carries emotional ramifications which sufficiently differentiate it from other procedures to allow for the imposition of some special requirements (such as mandatory counseling), Regulation 61-12 is in no way limited to regulatory requirements which are based upon or designed to address this or any other actual difference.

59. Turning to defendants' second justification, the court concludes that it too must be rejected. The State of South Carolina has a legitimate interest in protecting the health and welfare of women seeking abortions in the state. The State of South Carolina has a legitimate interest in promulgating uniform, minimum standards for the performance of invasive surgical procedures, including first trimester abortions, within the state. And the State of South Carolina could constitutionally require that abortions can only be lawfully performed by physicians licensed by the State Board of Medical Examiners to practice medicine pursuant to such uniform, minimum standards, thereby addressing any concern that unqualified, unlicensed physicians will come within its borders and establish unregulated abortion clinics performing unsafe abortion procedures. Nothing in this order concludes that the state may not do so.

60. Simply stated, the constitutional infirmity is not the regulation's proffered justification of promoting maternal health, which is a legitimate state interest, but the regulation's failure to utilize appropriate standards. The regulation singles out physicians and clinics where abortions are performed regularly, as part of the normal course of business and in relatively large numbers, and imposes upon them requirements which are not imposed upon comparable procedures and not even

upon all physicians who perform first trimester abortions. In addition, the regulation's requirements reach far beyond those justified by actual differences in the procedure, or by the medical nature and risks of the procedure. As support for its contention that the regulation reflects the current standard of care, defendants rely upon the testimony of its expert, as well as the testimony of Drs. Campbell and Buffkin who voluntarily comply with a number of its provisions. This court, however, places little weight on the testimony of defendants' expert, whose experience in this area is limited at best, and instead is persuaded by the credible testimony of Drs. Campbell and Buffkin (and the other well-qualified physicians) who testified that Regulation 61-12 will not serve to protect the health and welfare of pregnant women seeking abortions and may, on the contrary, act contrary to that stated goal.

61. Furthermore, defendants have offered no satisfactory explanation as to why the state standards applied to physicians' offices and clinics performing comparable procedures would not suffice to regulate first trimester abortion providers or ensure the health, safety and welfare of patients seeking abortions -- much less an acceptable basis for excluding physicians and facilities which perform first trimester abortions on a more infrequent basis. Even more inexplicable is the fact that the regulation would apply to providers of five or more medical abortions per month, a nonsurgical procedure consisting of a simple needle injection after which the patient is free to go home. Instead, the regulation has imposed requirements which far exceed medical necessity for the particular procedure at issue and in many respects exceed requirements which have previously been imposed upon medical facilities which perform procedures implicating higher risks and

potential complications than the relatively safe procedure sought to be regulated here.

62. In summary, Regulation 61-12 singles out all physicians and clinics who perform more than the occasional first trimester abortion and requires of them a license to operate their office or clinic. To obtain the license, the physician and clinics must comply with comprehensive mandates governing the physical layout of the clinic or office, the medical equipment which must be purchased and maintained, the cleaning, maintenance, and operation of the clinic and the requisite equipment, the management and training of the staff, and the type of medical care and tests which must be administered and offered to the patients. The onerous, and largely unnecessary, requirements of this regulation are neither "narrow enough in scope [nor] grounded in a sufficient factual context for [the court] to ascertain that there existed some relation between the classification and the purpose it [is now alleged to] serve[ ]." Romer, 517 U.S. at 632-33.

63. Accordingly, the court concludes that Regulation 61-12 singles out and places additional and onerous burdens upon abortion providers which are neither justified by actual differences nor rationally related to the state's legitimate interest in protecting the health and safety of women seeking first trimester abortions. Rather, "its sheer breadth is so discontinuous with the reasons offered for it that the [regulation] seems inexplicable by anything but animus toward the class that it affects." Romer, 517 U.S. at 632. The fact that the regulation was directed towards a politically unpopular group in the absence of any existing public health problem only bolsters this conclusion. See e.g. Romer, 517 U.S. at 632-33 & 634.

C. Severability

64. Finally, the court concludes that the infirm provisions of the regulation cannot be severed. The question of severability is determined under state law. See Dep't. of Treasury v. Fabe, 508 U.S. 491, 509 (1993). Under South Carolina law,

> [t]he test for severability is whether the constitutional portion of the statute remains complete in itself, wholly independent of that which is rejected, and is of such a character as that it may fairly be presumed that the Legislature would have passed it independent of that which is in conflict with the Constitution.

Thayer v. South Carolina Tax Comm'n, 413 S.E.2d 810, 815 (S.C. 1992) (internal citation and footnote omitted). If the statutory or regulatory scheme does not contain a specific severability clause, the legislature or agency is presumed to have "intended the act to be effected as an entirety or not at all." South Carolina Tax Comm'n v. United Oil Marketers, Inc., 412 S.E.2d 402, 405 (1991).

65. As an initial premise, the court notes that Regulation 61- 12 does not contain a severability provision, despite the fact that other DHEC regulations have included such provisions. See e.g., S.C. Code Ann. Regs. 61-4, Part 6, § 601 (Controlled Substances regulation); S.C. Code Ann. Regs. 61-21, § T (Sexually Transmitted Diseases regulation); S.C. Code Ann. Regs. 61-105 § B (Infectious Waste Management regulation). Furthermore, the absence of such a clause is consistent with the scheme of the enabling legislation and the nature of the regulation. It is apparent that the South

Carolina legislature intended for DHEC to create a comprehensive licensing scheme for abortion providers, as the legislation sets forth specific areas to be addressed by the regulation as a whole, and the text of the regulation is comprehensive and interdependent, reflecting a similar intent that it stand or fall as a whole.

66. Even if such a severability clause had been included, the court concludes that the regulation's extensive constitutional infirmities would render its enforcement impossible. First, although several of the regulation's specific provisions have been referenced in this order, it is the regulation as a whole that violates the fundamental right. The regulation was simply not, as a whole, designed to further the state's legitimate interest in maternal health, and the result is an over-inclusive, unnecessarily detailed regulatory scheme which unduly limits the discretion of licensed physicians and imposes numerous standards of medical care which are not medically indicated or, at a minimum, not medically indicated in every case. It lacks the requisite focus and restraint, and resembles instead what the testimony of the drafters reveals it to be -- a product of numerous other regulations and guidelines pasted together without meaningful oversight by persons knowledgeable in the practice of medicine or the performance of first trimester abortion procedures.

67. Finally, even were the court inclined to place the overall infirmities aside, severability is not possible. The regulation is permeated with provisions which are either not sufficiently supported by the state's interest in maternal health or not designed to further that goal, and any attempt by this court to sever even its most offensive provisions would gut the regulation and leave its remnants substantially incomprehensible. In short, the main provisions of this comprehensive regulation

and its purpose are clearly invalid, and this court is "'unable to untangle the constitutional from the unconstitutional." Ragsdale, 841 F.2d at 1375 (quoting Mahoning, 610 F.2d at 460). Accordingly, the court concludes that the violative portions of the regulation are not severable and that the regulation must be struck in its entirety.[18]

CONCLUSION

Having reviewed the regulation at issue, and the testimony and evidence regarding its promulgation and its probable effect upon the health of women who seek to obtain a first trimester abortion in the State of South Carolina, the court concludes that S.C. Code Regs. 61-12 is violative of the Due Process and Equal Protection Clauses of the United States Constitution and must be declared invalid.[19]

THEREFORE, IT IS ORDERED that Douglas E.

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[18] Earlier in this litigation, plaintiffs filed a motion for summary judgment, contending that discrete portions of the regulation were unconstitutionally vague, impermissibly delegated veto power over medical facility licensing to third parties, violated the Establishment Clause, and infringed upon the patients' rights to informational privacy. Plaintiffs did not raise a due process or equal protection challenge on summary judgment, seeking instead to request that the court strike the entire regulation because the provisions challenged on the alternative grounds were not severable. Upon review of this limited challenge, the court concluded that full development of the record was appropriate and that, even assuming that the provisions challenged were violative of the other constitutional standards, the remainder of the regulation would most likely survive a severability analysis. Hence, the motion was denied pending full development of the record at trial.

[19] Because Regulation 61-12 is violative of the Due Process and Equal Protection Clauses, it is unnecessary to separately consider plaintiffs' arguments that certain portions are unconstitutionally vague, violate the patients' confidentiality rights, and/or violate the Establishment Clause of the United States Constitution.

Bryant, in his official capacity as Commissioner of the South Carolina Department of Health and Environmental Control, the Governor of the State of South Carolina, in his official capacity, and Charles M. Condon, in his official capacity as Attorney General of the State of South Carolina, and their employees, agents and successors are hereby permanently enjoined from enforcing S.C. Code Regs. 61-12 as presently written.

IT IS SO ORDERED.

/s/
William B. Traxler, Jr.
United States Circuit Judge

February 5, 1999
Greenville, South Carolina

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
September 25, 2000

No. 99-1319
CA-96-1898-6-21

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions

Plaintiffs – Appellees

v.

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina;

Defendants – Appellants

GOVERNOR OF SOUTH CAROLINA

Defendant

No. 99-1710
CA-96-1898-6-21

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions

Plaintiffs – Appellees

v.

GOVERNOR OF SOUTH CAROLINA

Defendant – Appellant

and

DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina;

Defendants

No. 99-1725
CA-96-1898-6-21

GREENVILLE WOMEN'S CLINIC; CHARLESTON WOMEN'S MEDICAL CLINIC, INCORPORATED; WILLIAM LYNN, MD, on behalf of themselves and their patients seeking abortions

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DOUGLAS E. BRYANT, in his official capacity as Commissioner of South Carolina Department of Health and Environmental Control; CHARLES M. CONDON, in his official capacity as Attorney General of the State of South Carolina;

Defendants – Appellants
GOVERNOR OF SOUTH CAROLINA

Defendant

On Petition for Rehearing and Rehearing En Banc

Appellants filed a petition for rehearing and rehearing en banc.

Judge Hamilton voted to grant panel rehearing. Judges Niemeyer and Judge Smalkin voted to deny.

A member of the Court requested a poll on the petition for rehearing en banc. The poll failed to produce a majority of the judges in active service in favor of rehearing en banc. Chief Judge Wilkinson, and Judges Widener, Wilkins, Niemeyer, and Luttig voted to deny rehearing the case en banc, and Judges Michael, Motz, and King voted to rehear the case en banc. Judge Williams and Judge Traxler are disqualified and did not participate in the poll.

The Court denies the petition for rehearing and rehearing en banc.

Entered at the direction of Judge Niemeyer for the Court.

For the Court,

/s/ Patricia S. Connor

CLERK

PLAINTIFFS' EXHIBIT 10

Document No. 1903

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-7-130 and 260; 44-41-10 et seq., and 44-93-100

R.61-12. Minimum Standards for Licensing Clinics Performing Abortions During Second Trimester.

Synopsis:

The proposed amendment of R.61-12 will regulate facilities which perform five or more first trimester abortions per month and/or any second trimester abortion(s). The regulation is revised in its entirety and defines facilities wherein abortions are performed; reflects more specific requirements in the operation of abortion facilities, i.e., sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and follow-up care, as well as information contained in the "Women's Right to Know Act." It also addresses the disposal of fetal tissue. The title of R.61-12 will be changed to "Standards for Licensing Abortion Clinics.

Instructions:

Replace existing R.61-12 in its entirety with this amendment. Change the title to read: Standards for Licensing Abortion Clinics.

Text of Amendment:

61-12. STANDARDS FOR LICENSING ABORTION CLINICS.

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PART I. DEFINITIONS AND REQUIREMENTS FOR LICENSURE.

SECTION 101. Definitions. For the purposes of these regulations, the following definitions apply:

A. Abortion. The use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

B. Abortion Clinic. Any facility, other than a hospital as defined in Section 101.J, in which any second trimester or five or more first trimester abortions per month are performed.

C. Allied Health Professional. A person other than a physician who possesses specialized training and skill acquired by completing certain courses of study or intensive job-related training and, where applicable, has been duly licensed or registered by appropriate licensing or certification agencies. All allied health professionals must be supervised by a physician.

D. Conception. The fecundation of the ovum by the spermatozoa.

E. Consent. A signed and witnessed voluntary agreement to the performance of an abortion.

F. Department. The South Carolina Department of Health and Environmental Control.

G. Emancipated Minor. A minor who is or has been married or has by court order been freed from the care, custody, and control of her parents.

H. Fetal Death. Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

I. Fire Safety Authority. The State Fire Marshal, or his designee, who performs facility fire and safety inspections.

J. Hospital. An institution licensed for hospital operation by the Department in accordance with the provisions of Article 3, Chapter 7, Title 44, of the S.C. Code of Laws, 1976, as amended, and that has also been certified by the Department to be a suitable facility for the performance of abortion.

K. In Loco Parentis. Any person over the age of 18 who has placed him/herself in the position of a lawful parent by assuming obligations that are incidental to the parental relationship and has so served for a period of 60 days.

L. Licensee. The person, partnership, corporation, association, organization, or professional entity on whom rests the ultimate responsibility and authority for the conduct of the abortion clinic.

M. Medical Emergency. That condition which, on the basis of the physician's good faith judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the risk of her death or for which a delay will create serious risk of

substantial and irreversible impairment of major bodily functions.

N. Minor. A female under the age of 17.

O. Physician. A person licensed to practice medicine in this State.

P. Pregnancy. The condition of a woman carrying a fetus or embryo within her body.

Q. Probable Gestational Age of the Embryo or Fetus.

What, in the judgment of the attending physician, based upon the attending physician's examination and the woman's medical history, is with reasonable probability, the gestational age of the embryo or fetus at the time the abortion is planned to be performed. This estimate must be guided by recommendations found in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services, i.e., calculated from the first day of the last menstrual period.

R. Products of Conception. Fetal and embryonic tissues resulting from implantation in the uterus.

S. Trimester. A 12-week period of pregnancy.

1. First. The first 12 weeks of pregnancy commencing with conception rather than computed on the basis of the menstrual cycle.

2. Second. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.

3. Third. That portion of pregnancy beginning with the 25th week of gestation.

4. All other references in this regulation to gestational age will refer to that calculated from the first day of the last menstrual period as used in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services. The following is furnished to provide clarification of gestational age:

Calculation	Weeks of Gestational Age								
Conception	8	10	12	14	16	18	20	22	24
LMP	10	12	14	16	18	20	22	24	26

T. Viability. That stage of human development when the fetus is potentially able to live outside of the mother's womb with or without the aid of artificial life support systems. (Section 44-41-10(l) of the S.C. Code of Laws further states that "for the purposes of this chapter, a legal presumption is hereby created that viability occurs no sooner than the twenty-fourth week of pregnancy." The "twenty-fourth week," as stated in the S.C Code, is based on computation from date of conception, i.e., the twenty-sixth week from the first day of the last menstrual period.)

SECTION 102. License Requirements.

A. License. It shall be unlawful to operate an abortion clinic within South Carolina without possessing a valid license issued annually by the Department. (I)

B. Issuance of License. A license is issued pursuant to the provisions of Section 44-41-10 et seq., of the S.C.

Code of Laws of 1976, as amended, and these standards, and shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

C. Effective Date and Term of License. A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection has occurred.

D. Separate Licenses. Separate licenses are required for facilities not maintained on the same premises.

E. Licensing Fees. The initial and annual license fee shall be $500.00 for each licensed facility. Such fee shall be made payable to the Department. Fees are non-refundable.

F. Inspections. Each facility shall be inspected prior to initial licensure and at least annually thereafter by authorized representatives of the Department.

1. All licensed facilities are subject to inspection at any time.

2. Department inspectors shall have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies

of those documents required in the course of inspections or investigations. (II)

G. Initial License. A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide care to patients until it has been issued an initial license. When it is determined that the facility is in compliance with the requirements of these standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued. Chapter 9 of this regulation sets forth the prerequisites for initial licensure. (I)

H. License Renewal. Applicants for an annual license renewal shall file an application with the Department, pay a license fee, and undergo a licensing inspection.

I. Noncompliance. When noncompliance(s) with the licensing standards exists, the applicant or licensee shall be notified by the Department of the violation(s) and required to provide information as to how and when each violation will be corrected and how future occurrences may be prevented.

J. Facility Name. No proposed abortion clinic shall be named, nor may any existing abortion clinic have its name changed to, the same or similar name as any other abortion clinic licensed in the State. If it is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

K. Change of License. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;

2. Change of facility's name or address.

L. Exceptions to Licensing Standards. The Department may make exception(s) to these standards where it is determined that the health and welfare of the community require the services of the facility and that the exception(s), as granted, will have no significant adverse impact on the health, safety, or welfare of the facility's patients.

SECTION 103. Penalties.

When it determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice, may deny, suspend, or revoke licenses, or assess a monetary penalty. Under such conditions, the following shall apply:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or welfare of the patients of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a direct or immediate relationship to the health, safety or well-being of the facility's patients. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, i.e., (I) or (II). Violations of sections that are not annotated in that manner denote Class III violations.

E. In arriving at a decision to penalize a facility, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations.

F. When a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of
violation of

standard within a 24-month period:	MONETARY PENALTY RANGES		
FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 200-1000	$100-500	$0
2nd	500-2000	200-1000	100-500
3rd	1000-5000	500-2000	200-1000
4th	5000	1000-5000	500-2000
5th	5000	5000	1000-5000
6th	5000	5000	5000

G. Any facility that is dissatisfied with Department decisions may request a hearing pursuant to the Administrative Procedures Act.

PART II. ADMINISTRATION AND MANAGEMENT.

SECTION 201. Licensee. (II)

A. The licensee of each facility has the ultimate responsibility for the overall operation of the facility. Every facility shall be organized, equipped, staffed and administered to provide adequate care for each person admitted.

B. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the licensee of the facility. They shall include but not be limited to:

1. Purpose of the facility, to include scope and quality of services;

2. Ensuring compliance with all relevant federal, state, and local laws that govern operations of the facility;

3. Personnel policies and procedures, to include inservice training requirements;

4. The person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible;

5. Provision for annual review and evaluation of the facility's policies, procedures, management and operation;

6. Provision for a facility-wide quality improvement program to evaluate patient care. The program shall be ongoing, have statistical summaries, and have a written plan of implementation.

7. Patient rights and grievance procedures;

8. Functional safety and maintenance policies and procedures;

9. Incident reporting;

10. Consent must be informed, shall be obtained prior to the procedure, and shall include evidence of an explanation by a physician or allied health professional of the services offered and potential risks. Documentation of the informed consent must be filed in the patient's record.

SECTION 202. Administrator. (II)

An administrator shall be selected by the licensee and shall have the ability and authority to manage and administer the facility. Any change in the position of the administrator shall be reported immediately by the licensee to the

Department in writing. An individual shall be appointed in writing to act in the absence of the administrator.

SECTION 203. Administrative Records.

The following administrative documents and references shall be on file in the facility:

A. Current policies and procedures concerning the operation of the facility; (II)

B. Current memorandums of agreement and credentialing documentation.

C. A current copy of these regulations;

D. Annual elevator safety inspections, if applicable;

E. Annual heating, ventilation, and air conditioning inspection report.

SECTION 204. Personnel. (II)

Each facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients.

A. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate licensure, if applicable, and health and personal background of each employee.

B. Prior to performing job duties, all employees, to include volunteers who have direct patient contact within the clinic, shall have tuberculin skin testing

conducted unless a previously positive reaction is documented in millimeters. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is to be used. For employees/volunteers who have no documentation of a negative PPD result during the preceding 12 months, then the two-step procedure (one PPD test with negative result followed one to three weeks later by another PPD test) is required to establish a reliable baseline. If employees/volunteers have complete documentation of a negative PPD during the preceding 12 months (may be a single PPD or a two-step PPD), then a single PPD is acceptable to establish the baseline for current employment.

1. Persons with negative tuberculin skin tests who have direct contact with patients shall have an annual tuberculin skin test.

2. There is no need to perform an initial or routine chest X-ray on employees or volunteers with negative tuberculin tests who are asymptomatic.

3. Personnel with a positive reaction to the skin test shall have no patient contact until certified non-contagious by a physician.

4. Employees and volunteers with reactions of 10mm and over to the pre-employment tuberculin test, those new employees/volunteers who have previously-documented positive reactions, those with newly-converted skin tests and those with symptoms suggestive of TB (e.g., cough, weight loss, night sweats, fever, etc.), shall be given a chest X-ray to determine whether TB disease is present. If TB disease is diagnosed, appropriate treatment shall be given and contacts examined.

5. Personnel who are known or suspected to have TB shall be required to be evaluated by a physician and will not be allowed to return to work until they have been certified non-contagious by the physician.

6. Preventive treatment of personnel with new positive reactions is essential, and shall be considered for all infected employees/volunteers who have patient contact, unless specifically contraindicated. Routine annual chest X-rays of persons with positive reactions do not prevent TB and therefore are not a substitute for preventive treatment nor are required.

    a. Employees and volunteers who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of TB.

    b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest X-ray. These individuals must be informed of their lifelong risk of developing and transmitting TB to individuals in the institution and in the community. They shall be informed of symptoms which suggest the onset of TB, and the procedure to follow should such symptoms develop.

7. Post-exposure skin tests should be provided for tuberculin negative employees/volunteers within 12 weeks after termination of contact for any suspected exposure to a documented case of pulmonary TB.

8. A person shall be designated in writing at each facility to coordinate TB screening of personnel and any other TB control activities.

C. All professional and allied health professional staff members shall be currently certified with American Red Cross or American Heart Association CPR and capable of recognizing symptoms of distress. A professional or allied health professional staff member who is legally qualified to perform advanced cardiac life support must be present while patients are undergoing abortion procedures/ recovery in the facility. (I)

D. No employee or volunteer of the facility, while afflicted with any infected wounds, boils, sores, or an acute respiratory infection, or any other contagious disease or illness, shall work in any capacity in which there is a likelihood of such person transmitting disease to other individuals.

E. Each facility shall have and execute a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.

F. Inservice training programs shall be planned and provided for all employees and volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually:

1. Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as handwashing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members;

2. Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires:

3. Confidentiality of patient information and records, and protecting patient rights;

4. Licensing regulations.

G. Job Descriptions.

1. Written job descriptions that adequately describe the duties of every position shall be maintained.

2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.

3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.

H. A personnel file shall be maintained for each employee and for each volunteer. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the

individual's responsibilities and work assignments, and documentation of the person's orientation, in-service education, appropriate licensure, if applicable, and TB skin testing.

SECTION 205. Clinical Staff (II)

A. Physicians, nurses, and allied health professionals shall constitute the clinical staff.

B. The clinical staff shall meet at least quarterly to review and analyze their clinical experiences; minutes shall be maintained of such meetings.

C. Physicians. (I)

1. Abortions shall be performed only by physicians who are licensed to practice medicine in this State and who are properly qualified by training and experience to perform pregnancy termination procedures.

2. The facility shall enter into a signed written agreement with at least one physician board-certified in obstetrics and gynecology (if not one on staff) who has admitting privileges at one or more local hospitals with OB/GYN services to ensure his/her availability to the staff and patients during all operating hours.

3. A physician must remain on the premises until all patients are stable, and are ready for discharge. A physician must sign the discharge order and be readily accessible and available until the last patient has been discharged.

D. Nursing.

1. Nursing care shall be under the supervision of a registered nurse currently licensed in this State.

2. A registered nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period and until discharge by the attending physician.

3. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.

E. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

F. If ultrasonography is conducted in the clinic, the procedure shall be conducted by a physician or by an ultrasound technician who shall have documented evidence of completion of a training course in ultrasonography.

SECTION 206. Consent of the Patient. (I)

A physician shall not perform an abortion without first obtaining a signed and dated consent of the pregnant woman pursuant to the provisions of Section 44-41-30 of the S.C. Code of Laws, 1976, as amended.

SECTION 207. Abortion Performed Upon Minors. (I)

No person may perform an abortion upon a minor unless consent is obtained pursuant to the provisions of Section 44-41-31 of the S.C. Code of Laws, 1976, as amended.

SECTION 208. Dissemination of Information. (I)

Clinics must comply with the Woman's Right to Know Act, Section 44-41-310 et seq., of the S.C. Code of Laws, 1976, as amended, and maintain an adequate supply of current printed material from the Department which has not been altered in content.

SECTION 209. Patients' Rights (II)

A. The facility shall have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with the Department. These patients' rights shall be approved by the licensee.

B. Each facility shall display in a conspicuous place a copy of the patients' rights. In addition, a copy signed by the patient shall be included in the medical record.

PART III. PATIENT CARE.

SECTION 301. Policies and Procedures. (II)

Abortion clinics shall not serve patients whose needs exceed the resources and/or capabilities of the clinic. The facility shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients, to include but not limited to:

A. Admission criteria;

B. Physician and nurse responsibilities for the services offered;

C. Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications;

2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography required when gestational age is clinically estimated to be equal to or more than 14 weeks from the first day of the last menstrual period as established by the physician's performance of a bimanual physical examination. Policies and procedures should also indicate that ultrasound is recommended when gestational age is equal to or more than 12 weeks from the first day of the last menstrual period as established by the performance of a bimanual physical examination or if the physical examination and clinical evidence is inconclusive as to the gestational age.

D. The actual abortion procedure, to include the use of:

1. IV's;

2. Fluids;

3. Analgesia/anesthesia. General anesthesia shall be administered only by a certified registered nurse anesthetist, anesthesiologist, or dentist anesthetist or physician anesthetist.

4. Tissue examination/disposal.

E. Post-procedure care/recovery room procedures to include emergency care;

F. Provisions for the education of patient, family and others, as appropriate in pre and post-procedure care;

G. Plans for follow-up of patient after discharge from the facility, to include arrangements for post-operative visit, and specific instructions in case of emergency;

H. Management and appropriate referral of high-risk conditions;

I. Transfer of patients who, during the course of pregnancy termination are determined to need care beyond that of the facility;

J. Infection control and sanitation procedures to include duties and responsibilities of the infection control committee that shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility;

K. Registration of fetal death or death certificates, when applicable.

SECTION 302. Limitation of Services Offered by Abortion Clinics (I)

A. Abortions performed in abortion clinics shall be performed only on patients who are within 18 weeks from the first day of their last menstrual period. Those beyond 18 weeks shall be performed in a hospital. A licensed ambulatory surgical facility that

is also licensed as an abortion clinic may perform abortions on patients who are up to 26 weeks after the first day of their last menstrual period.

B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309.

SECTION 303. Pharmaceutical Services. (II)

Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state and local statutes and regulations.

A. Emergency Drugs:

1. Emergency Kit or Emergency Drugs. Each facility shall maintain an emergency kit or stock supply of drugs and medicines for the use of the physician in treating the emergency needs of patients. This kit or medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel. A listing of contents by drawer or shelf shall be placed on the cabinet or emergency cart to allow quick retrieval. Contents shall correspond with the inventory list. Drugs and equipment must be available within the facility to treat, as a minimum, the following conditions: (I)

a. Cardiac arrest;

b. Seizure;

c. Asthmatic attack;

d. Allergic reaction;

e. Narcotic toxicity;

f. Hypovolemic shock;

g. Vasovagal shock.

2. Drug Reference Sources. Each facility shall maintain reference sources for identifying and describing drugs and medicines.

B. Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility except by those authorized by law under orders of a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine.

C. Medicine Storage. Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to ±3 degrees Fahrenheit shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.

D. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be

located in such a manner as to prevent contamination of medicines being prepared for administration.

E. Controlled Substances Registration.

1. If a stock of controlled drugs is to be maintained at the facility, a physician on the clinic staff shall obtain an individual practitioner South Carolina Controlled Substances Registration and a Drug Enforcement Administration (DEA) Registration as registrant for the facility. This physician shall be responsible for the proper safeguarding and handling of controlled substances within the facility, and shall be certain that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control of the Department.

2. With a written power of attorney, this physician may grant permission to any other physician who possesses an individual practitioner South Carolina Controlled Substances Registration and a DEA Registration to administer, order for administration, or dispense any controlled substances maintained by the facility.

F. Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.

G. Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

SECTION 304. Laboratory Services. (II)

A. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).

1. Facilities for collecting specimens shall be available on site.

2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.

B. Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests are required:

1. Urinalysis including albumin and glucose examination;

2. Hematocrit or hemoglobin;

3. Determination of Rh factor (including the Du variant when the patient is Rh negative); Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative.

C. Other laboratory tests to be administered:

1. Testing for Chlamydia and gonorrhea;

2. Syphilis serology shall be offered;

3. A Papanicolaou procedure shall be offered;

4. Referral for chest X-ray, if indicated;

5. Other tests as deemed appropriate by the physician.

D. Aspirated tissues shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.

E. A written report of each laboratory test and examination shall be a part of the patient's record.

F. If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she should be administered fluids and transported immediately to a hospital that routinely performs crossmatches and transfuses patients.

G. All laboratory supplies shall be monitored for expiration dates, if applicable.

H. Products of conception resulting from the abortion procedure must be managed in accordance with requirements for pathological waste pursuant to Department R.61-105, Infectious Waste Management Regulations. All contaminated dressings and/or similar waste shall be properly disposed of in accordance with R.61-105.

SECTION 305. Emergency Care. (I)

A. All staff and/or consulting physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services or shall have in place documented arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.

B. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital.

C. The facility shall inform, in writing, the local ambulance service which provides emergency care and transport of patients, of the location of the facility, and the nature of medical problems which may result from abortions.

SECTION 306. Equipment and Supplies. (II)

There shall be appropriate equipment and supplies maintained for the patients to include but not limited to:

A. A bed or recliner suitable for recovery;

B. Oxygen with flow meters and masks or equivalent; (I)

C. Mechanical suction; (I)

D. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; (I)

E. Emergency medications, intravenous fluids, and related supplies and equipment; (I)

F. A clock with a sweep second hand;

G. Sterile suturing equipment and supplies;

H. Adjustable examination light;

I. Containers for soiled linen and waste materials with covers;

J. Refrigerator;

K. Appropriate equipment for the administering of general anesthesia, if applicable.

SECTION 307. Consultation. (II)

Arrangements shall be made for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed.

SECTION 308. Quality Improvement. (II)

A. The facility shall establish and implement a written plan for a quality improvement program for patient care. The plan shall specify the individual responsible for coordinating the quality improvement program and shall provide for ongoing monitoring of staff and patient care services.

B. There shall be an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

C. Evaluation of patient care throughout the facility shall be criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

D. The quality improvement process shall incorporate quarterly review of a minimum of five per cent of medical records of patients undergoing procedures during a given quarter, but not less than five records shall be reviewed.

E. The quality improvement process shall include evaluation by patients of care and services provided by the facility. If the families of patients are involved in the care and services provided by the facility, the quality improvement process shall include a means for obtaining input from families of patients.

F. The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including as a minimum, policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

G. The quality improvement program shall identify and establish indicators of quality care, specific to the facility, that shall be monitored and evaluated.

H. The results of the quality improvement program shall be submitted to the licensee for review at least annually and shall include at least the deficiencies found and recommendations for corrections or improvements. Deficiencies that jeopardize patient

safety shall be reported immediately in writing to the licensee.

SECTION 309. Requirements for Clinics Performing Abortions Beyond 14 Weeks. (I)

Clinics which perform abortions beyond 14 weeks from the first day of the last menstrual cycle shall, in addition to those requirements in all other sections of this regulation, have the following in place:

A. Physicians shall be board-certified or a candidate for board-certification in obstetrics and gynecology, general surgery, or family practice;

B. Physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services;

C. Laryngoscopes, endotracheal tubes, and defibrillator;

D. Laboratory tests/procedures shall include:

1. White blood count and determination of blood type;

2. Sickle cell, when indicated;

3. Ultrasonogram.

PART IV. MEDICAL RECORDS AND REPORTS.

SECTION 401. Medical Records. (II)

Medical records shall be maintained for all patients examined or treated in the clinic. The records shall be completely and accurately documented, readily available, and

systematically organized to facilitate the compilation and retrieval of information. All information shall be centralized in the patient's medical record. All entries shall be legibly written or typed, dated and signed.

A. The record shall include as a minimum the following information:

1. A face sheet with patient identification data, to include but not be limited to: name, address, telephone number, social security number, date of birth, father's and mother's names when patient is a minor, husband's name, and name, address and telephone number of person to be notified in the event of an emergency;

2. Signed consent for the procedure;

3. Date of initial examination;

4. Date of abortion;

5. Referring and attending physicians' names and phone numbers, if applicable;

6. Complete medical history to include medications currently being taken;

7. Physical examination, to the extent necessary to determine the health status of the patient, within 15 days of the procedure, including detail of findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period;

8. Results of diagnostic tests and/or examinations, e.g., X-ray, electrocardiography, clinical laboratory, pathology, consultations, ultrasound;

9. Pre-operative diagnosis;

10. Counselor's notes;

11. Physician's orders;

12. Complete record of abortion procedure to include:

    a. Vital signs, i.e., temperature, pulse, respiration, and blood pressure, prior to and following the procedure;

    b. Name of procedure performed;

    c. Anesthetic agent utilized;

    d. Name of attending physician performing the procedure;

    e. Names of clinical assistants in attendance, to include other physicians, physician's assistants, anesthetists, nurses, or specially-trained technicians;

    f. Signature of physician performing the procedure.

13. Nurses' notes;

14. Progress notes to include a post-anesthesia note if general anesthesia is utilized;

15. Attending physician's description of gross appearance of tissue removed;

16. Final diagnosis;

17. Condition on discharge;

18. Post-op orders and follow-up care;

19. Documented verification that the woman has been presented printed materials as required in the Woman's Right-to-Know Act;

20. In the case of an unemancipated minor or mentally incompetent person, a copy of the court order or written consent authorizing the abortion.

B. The attending physician must complete and sign the medical record within 72 hours following discharge.

SECTION 402. Records Storage.

All records shall be treated as confidential and shall be stored in a safe location for a minimum of 10 years. When records are stored in a location other than the clinic, and upon closure of the clinic, for any reason, the medical records shall be stored in a safe location for that minimum period, with the Department informed of that location. The medium in which the records are stored, e.g., optical disk, microfiche, is a facility decision.

SECTION 403. Reports. (II)

A. The following shall be reported to Vital Records and Public Health Statistics of this Department:

1. Any abortion performed, to be reported by the performing physician on the standard form for reporting abortions, within seven days after the abortion is performed;

2. A fetal death when the fetus has completed or passed the age or weight requiring a report, pursuant to the standards in Department R. 61-19, Vital Statistics.

B. A record of each accident or incident occurring in the facility which involves patients, staff, or visitors, including medication errors and adverse drug reactions, shall be prepared immediately. Accidents or incidents resulting in serious injury shall be reported, in writing, to the Department within 10 days of the occurrence; if a death occurs, other than a fetal death, it shall be reported to the Department not later than the next Department work day (Monday through Friday). Accidents and incidents that must be reported include, but are not limited to:

1. Those leading to hospitalization;

2. Those leading to death, other than a fetal death;

3. Adverse drug reactions.

PART V. FUNCTIONAL SAFETY AND MAINTENANCE. (II)

SECTION 501. Policies and Procedures.

A. Written policies and procedures shall be developed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.

B. The policies and procedures shall include, but not be limited to:

1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;

2. Provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;

3. Provisions for disseminating safety-related information to employees and users of the facility;

4. Provision for syringe and needle handling and storage.

5. Provisions for managing infectious waste from generation to disposal according to Regulation 61-105.

SECTION 502. Disaster Preparedness.

A. The facility shall have posted, in conspicuous places throughout the facility, a plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (I)

B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

SECTION 503. Maintenance.

A. Facility Maintenance. A facility's structure, its component parts, and all equipment such as elevators,

furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

B. Equipment Maintenance. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

PART VI. INFECTION CONTROL AND SANITATION. (II)

SECTION 601. General.

Policies and procedures shall be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

SECTION 602. Sterilization Procedures.

A. Adequate space shall be provided for storage, maintenance and distribution of sterile supplies and equipment.

B. Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled.

C. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

1. There must be documentation of each load run daily. A biological test of the autoclave shall be run daily and the results maintained on a log.

2. Each separate package of instruments to be sterilized must have internal and external chemical indicators.

3. The accuracy of instrumentation and equipment shall be provided by periodic calibration and/or preventive maintenance as necessary, but not less than annually, and a log maintained.

D. The policies and procedures shall indicate how the shelf life of a packaged sterile item is determined. Methods approved for use are:

1. Date of expiration being marked on the item; or

2. Event-related, i.e., day-to-day expiration, utilizing such wording as, "sterile unless the integrity of the package is compromised."

SECTION 603. Linen and Laundry.

A. An adequate supply of clean linen or disposable materials shall be maintained in order to insure change of linen on procedure tables between patients.

B. Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers.

C. A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

SECTION 604. Housekeeping.

A. General. A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.

B. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

C. Dry sweeping and dusting of walls and floors are prohibited.

SECTION 605. Refuse and Waste Disposal.

A. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed

and sanitized before being returned to work areas. Disposable type containers shall not be reused.

B. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

C. Immediately after emptying, containers for garbage shall be cleaned.

D. All waste meeting the definition of "infectious waste" as defined in Regulation 61-105 must be managed according to the requirements of that regulation.

SECTION 606. Outside Areas.

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

PART VII. FIRE PROTECTION AND PREVENTION. (I)

SECTION 701. Fire-fighting Equipment and Systems.

A. All facilities located outside a fire protected area shall have a contract with the nearest fire department.

B. An evacuation plan shall be posted in prominent places and staff members shall be trained as part of

their responsibilities to guide patients to the designated exits.

C. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested at least once each year, and more often if necessary to maintain them in serviceable condition.

D. Fire extinguishers of the proper type shall be installed in accordance with NFPA 10 (National Fire Protection Association) 10 requirements or as otherwise directed by fire authorities.

1. Fire extinguishers shall be kept in condition for instant use and shall be inspected monthly by facility staff with the date of inspection recorded on a tag affixed to the extinguisher.

2. Fire extinguishers shall be inspected and/or serviced annually by personnel licensed or certified to perform fire extinguisher servicing. Servicing/inspection records shall be kept on the fire extinguishers.

E. No portable electric, open flame, or unvented heaters shall be allowed in the facility.

F. Fire Drills.

1. A fire drill shall be conducted at least once every three months. New facilities shall conduct a fire drill within the first 48 hours of operation. Each employee shall participate in a fire drill at least twice each year.

2. Records of drills shall be maintained to report the date, time, description, and evaluation of the drill,

to include the names of participating staff and time for total evacuation.

G. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions.

H. Corridor and Stairway Illumination. Corridors, stairs and other means of egress shall be lighted at all times with a minimum of one foot-candle at finish floor level along the path of travel.

SECTION 702. Alarms.

A fire alarm system shall be provided in accordance with the provisions of NFPA 72. The fire alarm system shall be tested monthly and each detector tested annually. Records of all tests shall be retained for at least one year.

SECTION 703. Gas Storage.

Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes.

PART VIII. DESIGN AND CONSTRUCTION.

SECTION 801. General.

Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

SECTION 802. Local and State Codes and Standards. (II)

A. Facilities shall comply with pertinent local and state laws, codes, ordinances and standards with reference

to design and construction. Abortion clinics are categorized as a "business occupancy" as defined in the Standard Building Code. No facility will be licensed unless the Department has assurance that responsible local officials have approved the facility.

B. The Department uses as its basic codes: the Standard Building Code, Standard Plumbing Code, Standard Mechanical Code, and National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the requirements set forth in this regulation are also met.

SECTION 803. Submission of Plans and Specifications.

A. New Buildings, Additions or Major Alterations to Existing Buildings. (II)

1. When construction is contemplated either for new buildings, additions or major alterations to existing buildings, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulation requirements that apply to that project. Plans and specifications shall be submitted to the Department for review. Where the Standard Building Code or other regulations require fire-rated walls or other fire-rated structural elements, these plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal.

2. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the

Department. Any construction changes from the approved documents require approval by the Department.

B. Preliminary submission shall include the following:

1. Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection;

2. Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys;

3. Outline specifications listing a general description of construction including interior finishes and mechanical systems.

C. Final submission shall include the following:

Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout, if applicable.

D. In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

E. One complete set of as-built drawings shall be filed with DHEC.

SECTION 804. Licensure of Existing Structures. (II)

When an existing structure is contemplated for licensure it must meet the same building code requirements as a "new" facility (see Section 803.A). If an expansion or renovation to an existing facility is contemplated, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulatory requirements that apply to that project. The following shall be submitted to the Department:

A. If the physical dimensions of the building are affected, a plot plan in accordance with Section 803.B.1;

B. A floor plan in accordance with Section 803.B.2;

C. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

NOTE: Those existing abortion clinics that have been identified by the Department, through submission of regular reports of abortions performed, may be licensed in their current buildings. However, upon initial licensure, these facilities will be required to submit a plan that will bring them into full compliance with this chapter within two years from date of licensure.

SECTION 805. Minor Alterations in Licensed Facilities.

When alterations that involve construction that may affect walls, ceilings, floors, or fire and life safety are

contemplated, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards and determine if an architect need be involved.

SECTION 806. Location

A. Transportation. The facility must be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have parking space to reasonably satisfy the needs of patients, staff, and visitors.

C. Communications. A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

SECTION 807. Physical Facilities.

A. An adequate number of examination/procedure rooms shall be provided. A procedure room shall be sized, shaped, and arranged to allow unfettered movement for all persons involved in the procedure.

B. Each procedure room shall be provided:

1. A suitable gynecological procedure table;

2. Equipment necessary to treat patients for hemorrhage, shock, cardiac arrest and other

emergencies (an emergency "crash" cart in the immediate vicinity is acceptable); (I)

C. An area shall be provided for use by nurses in preparing medications for patients and keeping patient medical records. A room or cabinets shall be provided for storing medications and shall be kept locked except when medications are being prepared for administering. Narcotics shall be double-locked. An adequate supply of drugs shall be on hand at all times.

D. An adequate number of recovery room(s) or area(s) shall be provided. There shall be clear space on both sides and at the foot of each recovery bed/recliner to allow unencumbered movement by staff and patients.

1. There shall be a toilet room immediately accessible from the recovery area. This room shall contain a commode with grab bars or recessed hand-holds and handwashing lavatory, operable without the use of hands, soap dispenser with soap, and paper towel dispensers with paper towels, or hot air dryer;

2. There shall be a signal system for each patient bath and toilet that shall include an audible alarm that can be heard and location identified by staff;

3. There shall be a readily accessible safe and sanitary storage area for patients' clothing and personal effects;

4. There must be provisions to afford privacy upon request of a patient, e.g., curtains, screens, private room.

E. A room for the temporary storage of soiled linen and waste in covered containers shall be provided. This room shall be provided with at least 10 air changes per hour with all air continuously exhausted to the outside.

F. There must be an area to accommodate the sterilization procedures as described in Section 602. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for abortion. The area shall be arranged to prevent cross traffic of clean and dirty material. Air flow in this area shall be from the "clean" area toward the "dirty" area.

G. Suitable dressing room space shall be provided for physicians and nursing staff. Scrub facilities shall be provided and located conveniently to the procedure room(s).

H. Procedure and recovery room(s) shall be located on an exit access corridor that provides unimpeded, rapid access to an exit of the building. This exit must accommodate emergency transportation vehicles and equipment.

I. In multi-storied buildings where the facility is not located on the floor of entry to/exit from the building, there must be at least one elevator that serves the clinic floor(s). The elevator must accommodate emergency transportation equipment.

J. Adequate fixed or portable work surface areas shall be maintained for use in each procedure room.

K. Doors providing access into the facility and procedure room(s) shall be at least 36 inches wide to

accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least 48 inches wide.

L. Heating and ventilation.

1. Lighting, heating, and ventilation systems shall comply with local and state codes. There shall be approved equipment capable of maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.

2. The procedure room(s) and the recovery room(s) shall be provided a minimum of six air changes per hour. Air supplied to all areas shall be filtered through filters of at least 25 percent efficiency rating.

3. Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces that are not provided with operable windows or outside doors.

M. The entrance shall be at grade level or above, be sheltered from the weather, and accommodate wheelchairs.

N. There shall be adequate storage areas for supplies and other storage. Sterile supplies shall be stored separate from other supplies.

O. One or more janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment. Each shall contain a floor

receptor or service sink and storage space for housekeeping equipment and supplies.

P. A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

Q. There shall be at least two exits remote from each other.

R. Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

S. Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.

T. All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.

U. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

V. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

W. Wall bases in soiled equipment and material workrooms and other areas that are frequently subject

to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

X. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

Y. Interior finish materials shall comply with the Standard Building Code requirements for "business occupancy."

Z. Adequate space shall be provided for reception, waiting, interviewing, administrative, and business office functions. Space provided for interviewing and admitting shall be located and designed to provide privacy.

SECTION 808. Water Supply and Plumbing. (II)

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting. Patient and staff handwashing lavatories shall be supplied with hot water that shall be thermostatically controlled to a temperature between 100 and 125 degrees Fahrenheit.

B. Plumbing.

1. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code.

2. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections

between potable and non-potable water supplies. There shall be, at a minimum, an approved double-check assembly on the water supply to the facility.

SECTION 809. Emergency Power and Lighting Requirements.

A. The facility shall be equipped with automatic emergency power adequate to maintain the operation of lighting for procedure rooms, egress, fire detection equipment, and alarms. (I)

B. There shall be sufficient safe lighting for all activities, including suitable lighting for corridors. (II)

PART IX. PREREQUISITES FOR INITIAL LICENSURE.

Prior to admission of patients to, and issuance of a license for new facilities or additional procedure rooms, the following actions must be accomplished:

A. Plans and construction must be approved by the Division of Health Facilities Construction of this Department.

B. The facility shall submit a completed application for license on forms that shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:

1. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of this Department (includes satisfactory laboratory reports of water samples).

2. Approval from the appropriate building official stating that all applicable local codes and ordinances have been complied with.

    a. If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or

    b. If the facility is located outside town or city limits, a written letter of agreement with the nearest fire department that will provide protection and respond in case of fire at the facility shall be obtained. This letter shall indicate that they have the equipment, personnel, and/or agreements with other departments to adequately respond to this type of facility.

3. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility meets the requirements of the Standard Building Code.

4. Certification by the contractor that only the carpeting described in B.3 above was installed in the facility.

5. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.

6. Certification by the owner or contractor that only materials described in B.5 above were installed.

7. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.

8. Certification by the contractor that only the materials described in 7 above were installed.

9. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.

10. Certification by the contractor that the automatic sprinkler system, if required or installed, has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.

11. Certification that all medical gas systems have been properly installed and tested.

C. The facility must register as an infectious waste generator as outlined in Regulation 61-105.

D. Required personnel must be employed, available, trained, and capable of performing their duties.

E. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.

F. The facility must pay the required licensing fee.

PART X. GENERAL.

Conditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

Preliminary Assessment Report:

The Department estimates that the State and its political subdivisions will incur a fiscal impact of $7,525 by the promulgation of these regulations. Cost of implementation will be met by fees imposed by the proposed regulation.

Statement of Need and Reasonableness:

This revision is mandated by amendments to S.C. Code Sections 44-7-130 and -260; 44-41-10 et seq., and 44-93-100. The regulation is also needed to ensure the health, safety, and welfare of those women seeking to terminate pregnancies. This revision is reasonable because it requires only the basics that are needed to ensure that proper patient care is accomplished and in appropriately equipped facilities.

EXCERPTS FROM PLAINTIFFS' EXHIBIT 15:
American College of Gynecologists:
Standards: Obstetric-Gynecological Services, 7th ed. 1989

* * *

Surgical Services

Certain surgical procedures may be performed in an ambulatory care facility to conserve time and expense for the patient and to make efficient use of hospital facilities. A physician's office, an outpatient clinic, or a free-standing or hospital-based ambulatory surgical facility may be used as the setting. Procedures should be limited to those that can be performed safely within the constraints of staff expertise and physical facilities. If the patient has a major medical disorder, the gynecologist should obtain appropriate consultation before proceeding with a surgical procedure in an ambulatory care facility.

Informed consent should be obtained before any surgical procedure is performed. Upon discharge, the patient should be given adequate, preferably written, postoperative instructions, and arrangements made for routine and emergency follow-up care. The importance of a follow-up evaluation should be stressed during both the preoperative and the postoperative interviews.

Removed tissue should be submitted to a pathologist for examination. Routine pathologic examination of tissue may not be necessary, however, following the elective termination of a pregnancy in which embryonic or fetal parts can be identified. In such instances, the physician should simply record a description of the gross products of conception. The patient should be informed of the operative findings, including the results of tissue examination.

Physician's Office and Outpatient Clinic (Excluding Ambulatory Surgical Centers)

Only those surgical procedures that can be performed either without anesthesia or with only local anesthesia may be performed in the physician's office or in an outpatient clinic. When local anesthesia is used in these settings, equipment, drugs and qualified personnel should be available for emergency resuscitation.

Procedures commonly performed in a physician's office or in an outpatient clinic include, but are not limited to, the following:

- Abortion, uncomplicated, up to 14 weeks from last menstrual period
- Aspiration of a breast cyst
- Biopsy, aspiration, or washing of the endometrium
- Cervical polypectomy
- Cervical, vaginal, and vulvar biopsies
- Colposcopy
- Cryosurgery, fulguration, or vaporization of the cervix or vulva
- Culdocentesis
- Cystometric studies
- Cystoscopy
- Dilation and Curettage
- Evacuation of incomplete abortion, spontaneous and uncomplicated
- Hysterosalpingography
- Hysteroscopy
- Incision and drainage of vulvar or perineal abscesses
- Insertion of intrauterine contraceptive device
- Proctosigmoidoscopy
- Removal of skin lesions
- Tubal insufflation
- Urodynamic studies

- Uterine sounding

Free-Standing and Hospital-Based Facilities

Ambulatory surgical facilities that are free-standing or based in a hospital should maintain the same surgical, anesthetic, and personnel standards that hospitals do. In these facilities, surgical procedures may be performed under general or regional block anesthesia, but the postoperative recovery is expected to permit discharge on the same day. There should be a written policy providing for prompt emergency treatment or hospitalization of patients in the event of an unanticipated complication.

Procedures commonly performed in a free-standing or hospital-based ambulatory surgical facility include, but are not limited to, the following:

- Breast biopsy
- Cervical conization
- Colpoctomy
- Examination under anesthesia
- Extensive biopsies or extensive fulgurations of vulvar lesions
- Laparoscopy for diagnostic studies, tubal sterilization, or other surgical procedures, if laparotomy is not anticipated
- Laser surgery
- Marsupialization of a Bartholin duct abscess or cyst
- Minilaparotomy for sterilization
- Simple perineoplasty

Those procedures that may be performed in the physician's office or the outpatient clinic may also be performed in free-standing or hospital-based facilities.

A qualified anesthesiologist, another qualified physician, or a certified nurse-anesthetist who is supervised

by an anesthesiologist may administer general, epidural, or spinal anesthesia in an ambulatory surgical unit. When any form of anesthesia is used, trained personnel and proper equipment and drugs for cardiopulmonary resuscitation should be available. A physician, preferably the anesthesiologist, should be present in the ambulatory surgical facility until all patients have been discharged. This physician should oversee the postanesthetic recovery area and should share with the surgeon the responsibility for discharging patients or transferring them to the backup hospital.

Only patients at low risk should be considered candidates for ambulatory surgery. A preoperative history and physical examination should be completed no more than 2 weeks before the surgical procedure is to be performed. Preexisting or concurrent illness, medications, and adverse drug reactions that may have an effect on the operative procedure or anesthesia should be identified. Laboratory data should include hemoglobin level or hematocrit determination, urine screen, and in selected patients, other studies (e.g. chest, roentgenogram, electrocardiogram, and determination of electrolyte levels). The patient should be given preoperative instructions, especially regarding restrictions on food and fluid intake, and advised that noncompliance may result in cancellation of the procedure.

On the day of surgery, a physician should perform a pre anesthetic evaluation, including an interval history, medical record review, and heart and lung examination. The findings should be noted in the record.

Every free-standing or hospital-based ambulatory surgical facility should have a recovery area. During the recovery period, a member of the health care team should observe the patient continuously. This person should maintain a complete record of the patient's general condition, including vital signs, blood loss, and occurrence of complications. The patient should remain in the area until recovery is sufficient to permit safe discharge in the company

of a responsible adult. Upon discharge, the patient should be given instructions about medications, follow-up care, signs and symptoms of common complications, and procedures to obtain emergency care and advice.

Abortion

Ambulatory care facilities should meet the same standards of care for abortion services as for other surgical procedures. Physicians who perform abortions in their offices should provide for prompt emergency treatment or hospitalization of patients in the event that a complication occurs. Clinics and free-standing ambulatory care facilities should have a mechanism for the transfer of patients requiring emergency treatment to a nearby hospital.

Generally, abortions in the physician's office or outpatient clinic should be limited to those performed within 14 weeks from the first day of the last menstrual period. In a hospital-based or free-standing surgical facility, abortions should generally be limited to those performed within 18 weeks from the last menstrual period. In a hospital-based facility where surgical, recovery and emergency response capabilities are comprehensive, however, abortions may be performed beyond this time.

Prior to the procedure, the woman should be counseled on the options for the management of an unwanted pregnancy. She should be allowed sufficient time for reflection before she makes an informed decision. If she has received counseling elsewhere, the physician who is to perform the abortion should verify that the counseling has taken place.

In addition to the history, physical examination, and indicated laboratory procedures, Rh factor should be determined and an antibody screen performed on a woman who is to have an abortion. Every unsensitized Rh-negative woman who has an abortion should receive Rho(D)

immunoglobulin. Before the patient's release from the facility, aspirated tissue should be examined to verify that villi or fetal parts are present. If villi or fetal parts cannot be identified with certainty, the tissue specimen should be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy. If the tissue suggests a molar pregnancy, the patient should be so informed and appropriate follow-up instituted. The patient should receive instructions in the use of family planning methods.

Administration

Physician's Office and Outpatient Clinic

Medical Records

Physicians' offices and outpatient clinics should maintain an accurate medical record for each patient. The record should be legible, concise, cogent, and complete. In addition, the record should allow easy assessment of the care provided to determine whether the patient's health care needs have been managed effectively. Because medical practice frequently involves several physicians and other professionals and because the record serves as a vehicle for communication among all members of the health care team, it should be readily accessible.

At the initial visit, a comprehensive data base and plan of therapy should be established; these should be updated at each subsequent visit. Correspondence, operative notes, and laboratory data should be reviewed and filed chronologically in the patient's medical record. Any pertinent data regarding changes in the patient's health status or inpatient care should be recorded; this may take the form of a diagnostic summary.

All medical information should be confidential and the record secure. All records should be retained for the

period of time prescribed by law and by good medical practice.

Personnel

Administrative and professional personnel requirements in physicians' offices and outpatient clinics depend on the patient load, pattern of practice, and type of facility. The members of the health care team should participate in specific areas of care according to their training and within written definitions of their responsibilities. Policies and responsibilities should be reviewed and revised periodically. Regular meetings of personnel should be encouraged, and there should be an ongoing program for in-service training.

Facilities and Equipment

The type of practice and patient volume determine the specific physical facilities and equipment required in a physician's office or outpatient clinic, but certain items should be reasonably available for the care of patients in any office or clinic setting. For example, the reception area should have comfortable seating, patient education materials, and conveniently located toilet facilities. Sufficient space should be provided to ensure that medical and financial records are handled and stored with security and confidentiality.

A comfortable and private area should be provided for interviews and for counseling the patient or her family. Each consultation room should contain at least a desk or table with two chairs. The physician's office may serve as a consultation room. Separate rooms, other than the physician's office, should be available for use by nurses, social workers, health educators, and other members of the health care team.

The following equipment should be accessible to, although not necessarily located in, each examining room:

- Biopsy instruments
- Instruments for vaginal and rectal examination
- Microscope
- Sphygmomanometer
- Stethoscope
- Reflex hammer
- Opthalmoscope
- Scale
- Supplies for obtaining
  --Specimens and cultures
  --Wet slide preparations and bacterial smears
  --Cytologic studies
- Equipment necessary for diagnostic studies and operative procedures performed in the facility

When local anesthesia is used, the following drugs and equipment should be available for emergency resuscitation:

- Positive pressure device and a source of oxygen
- Intravenous equipment and fluids
- Suction apparatus
- Laryngoscope with assorted airways
- Vasopressor substances or other drugs

The exact number of examining rooms required depends on the patient load and they type of practice; even a solo physician's office, however, should have at least two examination rooms. The following equipment should be available in each examining room:

- Screens to permit patient privacy
- Hand-washing facilities and paper towels
- Examination table with suitable disposable cover and a stool
- Examination light

- Gynecologic examination equipment and supplies
- Work counter or table
- Small desk, table, or shelf for writing
- Storage cabinet

The utility room area should contain the following facilities:

- Work counter
- Hand-washing facilities and paper towels
- Sink
- Closed cabinets for storage
- Locked medicine cabinets
- Refrigerator
- Facilities for sterilization (unless central sterilization facilities are available)
- Waste receptacle

Specific plans and procedures should be established to protect the health and safety of patients and personnel. They should include the following:

- Procedures for controlling and disposing of needles, syringes, glass, knife blades, and contaminated waste supplies
- Methods for storing, preparing, and administering drugs, when applicable
- Plans for handling reasonably foreseeable emergencies, including methods for transferring a patient to a nearby hospital
- Procedures for evacuation of patients in an emergency and for proper use of safety, emergency and fire equipment
- Plans for training personnel in cardiopulmonary resuscitation

EXCERPTS FROM PLAINTIFFS' EXHIBIT 16:
American College of Gynecologists:
Guidelines for Women's Health Care (1996)

[iii]

The information in Guidelines for Women's Health Care should not be viewed as a body of rigid rules. The guidelines are general and intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution, or the type of practice. Variations and innovations that improve the quality of patient care are to be encouraged rather than restricted. The purpose of these guidelines will be well served if they provide a firm basis on which local norms may be built.

* * *

[34]

OFFICE CARE

The obstetrician-gynecologist often serves as a woman's point of entry into the health care system as her main source of continuity in health care. A modern approach to obstetric-gynecologic office practice requires an organized system that can administer to a broad range of women's health care needs–medical, surgical, and psychosocial. The scope of services physicians provide will vary from practice to practice (see box). How physicians define their scope of practice will affect how their office is organized and managed. The facility should be organized in a manner that provides high quality, efficient services and includes methods to measure, assess, and improve the quality of care administered.

MANAGEMENT

Common to all office medical practices are certain principles and processes necessary to maintain an efficient and safe atmosphere in which to practice medicine. The following principles of management are recommended as guide-

* * *

[table omitted]

lines that may be followed regardless of the size of the office or clinic or the scope of women's health care to be administered.

Personnel

An office-based medical practice or clinic should have an office manager or other key office person assigned to personnel management. A personnel manual should be established for the entire office staff. Written job descriptions should exist for each staff position. Previous employment references should be checked for all new employees. Current licensure verification is mandatory for all licensed personnel. Job descriptions should be reviewed periodically to be certain that staff members are not performing tasks beyond their licensing or training.

Regular office staff meetings should be held for all office staff. These meetings can be useful in improving staff communication and in exploring ways to enhance patient relations and communications. The office staff meeting is the ideal setting to discuss quality assessment issues and risk management and to provide continuing medical education for both clinical and nonclinical staff members. Staff should be encouraged to make suggestions for improving office procedures. Office staff should be reminded periodically of the need for maintaining strict confidentiality of all patient contacts, treatment, and records. A written personnel policy

should exist that states that any violation of patient confidentiality is grounds for employee dismissal. Physician's offices should also establish policies on sexual harassment and make all personnel aware of them (see "Hospital Care")

Facilities

The office or clinic, no matter how small or how large, should be well organized and clean. The reception area should be pleasantly decorated and comfortable and should have adequate seating capacity to accommodate patients. Current general interest reading material and patient education materials should be available. The reception area should be separate from yet visible to the receptionist. Ideally, patients in the reception area should not be able to overhear telephone conversations or business conducted by the receptionist. A telephone should be available for patients to make outgoing calls. Restrooms and patient changing area that is adequate in space for undressing and dressing should be available. Accessories such as mirrors and hangers for a patient's personal belongings should be provided in the changing area.

There should be a comfortable area that is private for discussing confidential information and for interviewing and counseling the patient or her family. The physician's office may serve as a consultation room; however, separate rooms, other than the physician's office and examining rooms, should be available for use by nurses, social workers, health educators, or other members of the health care team. The number of examining rooms will depend upon the patient profile and the size of the practice. A minimum of two examination rooms per physician should be available. There should be a utility area, separate from the examination rooms, equipped with work counters, closed cabinets for storage, locked medicine cabinets, a refrigerator, and facilities for sterilization and handwashing.

Medical Records

An accurate medical record should be maintained for each patient. The patient's name should appear on each page of the record, and pertinent information should be firmly attached. The record should be legible, consise, cogent and complete. A problem list should be maintained. The record should allow easy assessment of the care provided to determine whether the patient's health care needs have been identified and managed effectively. Entries by all health care workers should be signed or initialed and dated. Any abbreviations should be clear to all health care workers using the patient's medical record.

Medical records should be organized in a consistent manner. A system should be in place to avoid misplaced or misfiled medical records. The medical staff should be made aware of the need for strict confidentiality of a patient's medical records.

There should be an established protocol for handling requests for records by the patient, her family, an attorney, and insurance company, or another third party. A signed authorization should be obtained from the patient prior to the release of any medical information contained in her medical record. Only copies should be transmitted; the original record should be retained in the office. When copies of the medical records are transferred to the hospital, as with prenatal records transferred prior to delivery, the hospital should be expected to maintain the confidentiality of the patient's records.

Where feasible, patient financial records should be kept in a separate confidential file, apart from the patient's medical record. All correspondence or notation of conversations between physicians and professional liability insurance carriers or defense counsel pertaining to a patient should be kept in a confidential file, separate from the patient's medical record.

Patient Communication

Informed consent is the cornerstone of patient communication. The physician is responsible for securing the patient's informed consent. The risks, benefits and alternatives of the proposed procedure or treatment should be discussed with the patient. Patient education information, when available, should be provided to supplement informed consent and discussions relating to specific treatments, operations and procedures. The patient should be informed of the common adverse effects of prescribed drugs, as well as the importance of reading the patient package inserts for drugs or devices. All informed consent discussions and materials should be documented appropriately in the patient's record. If a patient refuses a recommended test or procedure, such refusal should also be documented.

Physicians should also comply with specific state and federal informed consent laws and regulations that apply to specific treatments or procedures. This may include informing patients of risks and benefits contained in the laws and having patients sign an approved consent form. Specific additional requirements may apply to patients under 21 years of age.

An established protocol should exist to ensure that patients are informed of all significant abnormal test results. This notification should be documented in the patient's record. A method should exist for monitoring patients' compliance with recommendations made based on abnormal test results. The patient or her family should be given individualized instructions for continuing care following office operative procedures, and this instruction should be documented in the patient's medical record
An established protocol should also exist for follow-up with any patient whose disease or condition may be life threatening or have a serious effect on her life if she fails to keep appointments. Missed appointments as well as

noncompliance with medical advice and refusal of a recommended test or procedure should be documented in the patient's record.

All telephone contact regarding clinical matters should be documented in the patient's medical record. A method should be established to document or log such contacts both during and after office hours. An answering service for telephone calls or specific office equipment to receive and transmit patient messages after normal office hours should be in place. The physician should be notified when a telephone message from a patient specifically requests that care be provided by that physician. Ideally, the office staff should inform the patient of an approximate time when the call would be returned by the physician. All telephone prescription renewals should be verified by the physician.

The physician should be aware of legal and any managed care contractual requirements for termination of the physician-patient relationship. Documentation of all steps undertaken to terminate the physician-patient relationship should be present in the patient's medical record.

A protocol should exist for processing pertinent clinical information that may arrive by telephone, facsimile, or mail. A clear procedure should be in place to ensure that clinical information, such as laboratory, radiology, and pathology reports, and pertinent patient telephone messages are reviewed by the health care team. All such information should be initialed or signed and dated by the physician or qualified health care worker, then filed in the medical record.

Billing and Collections

During the initial visit, a patient should be advised of customary fees. Billing and third-party insurance procedures should routinely be discussed with each patient at this visit. An area of the office should be provided where these matters can be discussed with the patient in confidence. If a patient

questions the professional fees, the physician should be informed and the physician should advice the staff as to the appropriate method of handling the problem. A specific staff person should be assigned responsibility for following up on patients' financial problems or complaints. If an outside billing and collection service is used for delinquent accounts, the physician should be informed before the account is assigned to such an agency.

Appointments, Scheduling, and Patient Flow

The most efficient method of managing patient flow in an office setting or clinic is by appointment. Appointments should be booked realistically to maintain the physician's schedule and allow ample time for emergency appointments. The office personnel and physicians should establish a realistic goal of minimizing waiting time. The average time a physician spends with a patient for various procedures (new patient visit, yearly checkup, gynecologic office procedure) can be analyzed easily, and scheduling can be based on this information. The scheduling should be analyzed periodically to ensure minimal patient waiting. There should be established procedures for the following circumstances:

- Rescheduling missed or canceled appointments
- Informing patients when their appointments will be delayed significantly or when an emergency situation may prevent the physician from keeping appointments
- Processing patients in a timely manner
- Guiding patients to specific areas of the office (laboratory, insurance office, etc.)

* * *

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Procedures Commonly Performed in a Physician's Office or Outpatient Clinic

- Early abortion
- Aspiration of breast cyst
- Biopsy, aspiration, or washing of the endometrium
- Cervical polypectomy
- Cervical, vaginal and vulvar biopsies
- Colposcopy
- Cryosurgery of the cervix, vulva or vagina
- Culdocentesis
- Cystoscopy and urethroscopy
- Dilation and curettage of the uterus
- Evacuation of incomplete abortion (spontaneous and uncomplicated)
- Hysterosalpingography
- Hysteroscopy, diagnostic
- Incision and drainage of vulvar or perineal abscesses
- Insertion and removal or contraceptive implants
- Insertion of intrauterine contraceptive devices
- Laser vaporization and excision of the cervix, vulva or vagina
- Loop electrosurgical excision procedures of the cervix, vulva or vagina
- Marsupialization of cysts of the Bartholin gland
- Proctosigmoidoscopy
- Removal of skin lesions

* * *

ABORTION

In 1973 Roe v. Wade gave women the constitutional right to abortion. It recognized states' rights to limit access to abortion services after the first trimester to protect the health of the mother and to protect the fetus after viability (in 1973 considered to be the end of the second trimester). Since 1973, the U.S. Supreme Court has handed down numerous decisions pertaining to abortion, markedly influencing national abortion policy and making the states key players in developing abortion policies. (Table 3-5)

Approximately one quarter–1.6 million–of all pregnancies in the united states are terminated by abortion. Of these, 90% are performed in the first trimester, with approximately 60% provided to women who are younger than 25 years of age. The highest rates occur among teenagers, 96% of whom are unmarried. In the United States, fewer than 1% of induced abortions are performed after 20 weeks.

When faced with an unintended pregnancy, a woman has the right to choose to have an abortion and should be unencumbered by such obstacles as the following:

- Parental notification and consent
- Bans on public funding for abortion facilities and services
- Stricter facility regulations for abortion than for other surgical procedures of similar risk
- Harassment of and violence against providers of services
- Lack of availability of providers

Physicians need to be aware of any limitation on abortion services in their jurisdiction.

RISKS

Properly performed abortion poses minimal risk to women. The risk of serious complications from first-trimester abortion is less than 0.5%, and abortion is 25 times less likely to result in maternal death than carrying a pregnancy to term. There are no data to indicate that long-term negative psychologic reactions occur in women who have abortions.

The safest method of abortion in the united states is first semester suction curettage. (Mifepristone [RU-486] is a safe alternative but is currently available in this country only under research protocol.) Dilation and evacuation methods have become recognized as safer than instillation methods for second-trimester abortions, but only in experienced hands.

FACILITIES

Health professionals have an obligation to ensure that the health and well-being (both physical and emotional) of the patient are taken into account when abortion services are provided. Abortions should be performed in a humane, sensitive, medically safe way. All legal requirements must be met, and clinicians who perform abortions should be aware of state statutes and regulations regarding abortion services.

Abortion may be performed in a physician's office, an outpatient clinic, a freestanding ambulatory surgical facility, or a hospital. For later second-trimester or instillation abortions or for patients with other risk factors, a hospital or ambulatory surgical facility is preferred and in some states required.

Ambulatory care facilities should meet the same standards of care for abortion services as for other surgical procedures. Physicians who perform abortions in their offices should provide for prompt emergency treatment or hospitalization of patients in the event that a complication occurs. Clinics and freestanding ambulatory care facilities should have an established mechanism for transferring

patients who require emergency treatment to a nearby hospital.

MANAGEMENT

Before an abortion, the patient should be counseled on her options for the management of the unwanted pregnancy. She should be allowed to make an independent decision and must give informed consent for the procedure. If she has received counseling elsewhere, the physician who is to perform the procedure should verify that appropriate counseling has taken place.

Pregnancy and gestational age should be confirmed before the procedure. If the pregnancy is thought to be 18 or more weeks of gestation, the gestational age should be confirmed with ultrasonography. In addition to the history, physical examination, and indicated laboratory procedures, the patients Rho(D) status should be determined and an antibody screen performed. Every nonsensitized D-negative woman who has an abortion should receive D immune globulin. Studies suggest that antibiotics used prophylactically in conjunction with induced abortion decrease morbidity. Before the patient is released from the facility, aspirated tissue should be examined to verify that villi or fetal parts are present. If villi or fetal parts cannot be identified with certainty, the tissue specimen should be sent for further histologic examination and the patient alerted to the possibility of an ectopic pregnancy. If the tissue suggests a molar pregnancy, the patient should be so informed and appropriate management instituted.

The patient should receive information on the use of family planning methods. Arrangements should be made for follow-up care, and the patient should be provided with written instructions for care if complications arise.

SEXUALLY TRANSMISSIBLE DISEASES

Sexually transmissible diseases include a variety of infections diseases that involve both the upper and the lower

genital tract, as well as a number of other infections diseases such as hepatitis B and human immunodeficiency virus (HIV) infection. Sexually transmissible diseases are considered public health issues, and physicians should be aware of state statutes and regulations governing their need to be reported.

Multiple diseases can be transmitted through sexual activity. For some diseases (e.g. syphilis, gonorrhea, chlamydial infection, herpes) sexual activity is almost the only method of transmission, whereas for other diseases (e.g. HIV infection), other methods of transmission are also common. For other diseases (e.g. hepatitis B), sexual activity is the method of transmission in only a minority of cases. Good evidence is available to support the inclusion of *Mycoplasma hominis* infections, bacterial vaginosis, *Trichomonas vaginalis,* human papillomavirus (HPV) infection, and sometimes *Candida* sp. Infections as agents that can be transmitted through sexual activity.

HISTORY

Certain life styles are associated with increased risk of genital infections. Women who have had multiple sexual partners and those who use illicit drugs have an increased risk of exposure to one or more infectious agents. Multiple STD infections are common.

A history of recurrent genital tract infections may also indicate other serious medical disease. Recurrent, difficult-to-treat yeast infections may also be an early sign of HIV infection. Abnormal bleeding may be associated with upper genital infection (chronic endometriosis)

EVALUATION AND TREATMENT

Screening should be done on the basis of risk factors. Cultures from the vagina or cervix add little useful information except in cases of gonorrhea and chlamydial infection. In most cases, treatment should conform with

guidelines issued by the Centers for Disease Control and Prevention.

Treatment of male sexual partners is a keystone in the prevention of transmission of and reinfection with certain STDs. Physicians are frequently requested to provide a prescription for the patient's partner without examination. There is no clear policy concerning the appropriateness of such action. In most cases, such a prescription will result in treatment without complication. An adverse reaction to the medication is uncommon but may result in a significant health hazard to the partner. Each physician must decide whether providing such prescriptions is appropriate. The Centers for Disease Control and Prevention addresses the difficult issue of partner treatment in its *1993 Sexually Transmitted Disease Guidelines*. This document states:

> Patients with STDs should insure that their sex partners, including those without symptoms, are referred for evaluation. Providers should be prepared to assist in that effort.... Breaking the train of transmission is crucial to STD control.

PLAINTIFFS' EXHIBIT 26:
Letter to George R. Moore, Director Outpatient and Home Care Program, Division of Health Licensing, South Carolina Dept. of Health and Environmental Control from General Counsel for the American College of Obstetricians and Gynecologists dated May 3, 1995

Office of the General Counsel
Telephone (202) 863-2598
Fax (202) 863-4980

**The
American
College of
Obstetricians and
Gynecologists**

May 3, 1995

George R. Moore, Director
Outpatient and Home Care Program
Division of Health Licensing
South Carolina Dept. of Health and
Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Mr. Moore:

The American College of Obstetricians and Gynecologists welcomes the opportunity to comment on the proposed regulations for licensing abortion clinics that you circulated on March 22, 1995.

The College is concerned that most of the new requirements will not enhance patient well-being or safety; yet require such extensive changes to office procedures, staffing

patterns, and physician facilities that most physician's offices will not be able to comply with them.

The likely consequence is that many physicians who now perform abortions will stop doing these procedures, making abortions less accessible to women in South Carolina. The regulations' effect would be to create an undue burden upon women's constitutional right to obtain abortions free from unlawful state interference, as defined by U.S. Supreme court decisions.

A first trimester and early second trimester abortion is a legal, safe procedure that can be performed in a physician's office. Induced abortion is one of the most common and safest surgical procedures, and may be performed in a physician's office, outpatient clinic, free-standing ambulatory surgical facility or hospital. For uncomplicated abortions performed up to 14 weeks, which represent over 90% of the abortions performed in this country, a physician's office or clinic is the most appropriate setting. The College's Standards for Obstetric – Gynecologic Services (7th Edition 1989) states:

> "Ambulatory care facilities should meet the same standards of care for abortion services as for other surgical procedures. Physicians who perform abortions in their offices should provide for prompt emergency treatment or hospitalization of patients in the event that a complication occurs. Clinics and free-standing ambulatory care facilities should have a mechanism for the transfer of patients requiring emergency treatment to a nearby hospital."
>
> Generally, abortions in the physician's office or outpatient clinic should be limited to those

> performed within 14 weeks from the first day of the last menstrual period. In a hospital-based or free-standing surgical facility, abortions should generally be limited to those performed within 18 weeks from the last menstrual period. In a hospital-based facility where surgical, recovery and emergency response capabilities are comprehensive, however, abortions may be performed beyond this time."

While not attempting to do an exhaustive analysis of the proposed regulations at this preliminary stage of development, I would like to mention a few areas of concern.

The proposed regulations impose a variety of detailed administrative requirements upon facilities that are particularly onerous for the physician's office, with no demonstrated benefit to patient care. These include a required written quality improvement program with a multi-disciplinary committee that does a quarterly record review (Section 310). The provision in Section 305 that the clinical staff be organized, have approved bylaws, meet at least quarterly, and keep minutes, makes no sense in the office setting. There is no patient care justification for the requirement of written job descriptions for all office employees, or for the requirement that all employees medical records be made available for inspection (Section 204). To the contrary, this last requirement appears to violate the confidential nature of medical records. The cumulative impact of these administrative requirements on a private medical practice is dramatic. Not only is compliance expensive, it also is time consuming, taking away from time available for patient care.

The new regulations also contain additional requirements related to office equipment and architectural specifications

that do not apply to offices where minor surgical procedures other than abortion are done. There is no apparent need for these. Examples include the Section 807(k) requirements that doors be 44 inches wide, that there be blanket warmers (Section 304), and that procedure room ceilings be 9 feet high (Section 807).

Finally, certain regulatory requirements either dictate medical services that must be provided to women seeking abortions or limit patients' access to abortion on the grounds of certain medical conditions. These medical provisions go far beyond the scope of clinic regulation by dictating medical care and curtailing a physician's exercise of medical judgment. Section 302 prohibits abortions outside the hospital setting for women with certain medical conditions, but the need for women with these conditions to be hospitalized for abortions is not supported by the medical literature. In most of these cases, abortions can be done safely in an outpatient setting. There is no justification for interfering, through regulations, with the physician's medical judgment about what medical condition, on a patient by patient basis, create a high risk situation demanding hospitalization. In section 309, many of the mandated tests are not necessary prior to an abortion being performed. For example, every patient need not have a pap test prior to an abortion procedure if one has been done within the recent past. These requirements will add significantly to the cost of abortion.

Physicians' offices and ambulatory care centers are currently subject to specific state licensing and other regulatory requirements designed to assure patient safety, and to Federal regulatory provisions such as CLIA, OSHA, and Medicare requirements. To single out those facilities that offer early abortions as being subject to additional mandatory expensive requirements seems only designed for one purpose: to limit physicians' ability to offer these services.

The American College of Obstetricians and Gynecologists urges the State of South Carolina to reconsider these regulations as they apply to abortions prior to 18 weeks gestation, and not to adopt them for this category. We would be happy to work with you on this issue.

Sincerely,

/s/_____
Ann E. Allen
General Counsel

EXCERPTS FROM DEFENDANTS' EXHIBIT 18:
National Medical Division,
Planned Parenthood Federation of America, Inc.:
Manual of Medical Standards and Guidelines
(Revised March 1994)

* * *

PHYSICAL FACILITIES

The physical facility, whether on or off site, must satisfy applicable state and local regulations, if any, for physician's office or ambulatory surgical centers. The facility must have:

1. adequate, private space specifically designated for interviewing, counseling and medical evaluation;

2. dressing rooms for staff and patients, and appropriate lavatory facilities;

3. facilities for pre-procedure hand washing;

4. procedure room(s) large enough to accommodate a stretcher or gurney;

5. adequate lighting and ventilation for abortion procedures;

6. a surgical or gynecologic examination table;

7. post-procedure recovery room, properly supervised, staffed and equipped;

8. emergency exit to accommodate a stretcher or gurney;

9. facilities for sterilization of instruments.

* * *

PERSONNEL

The following personnel must be available:

* * *

2. A licensed health professional to supervise the recovery area, to assist in the procedure room, as needed, or to perform other functions as required by state law.

* * *

MEDICAL SCREENING AND EVALUATION

* * *

3. Laboratory testing shall consist of:

* * *

d. gonorrhea and chlamydia evaluation (history and examination: testing as indicated);

* * *

EXCERPT FROM DEFENDANTS' EXHIBIT 18:

National Abortion Federation

A Resource for NAF Members Faced with Legislative Bodies or Regulatory Agencies Proposing Regulation of Abortion Service

Abortion is one of the safest and most commonly performed surgical procedures for women. Every year in the United States, approximately 1.0 million women terminate a pregnancy. Abortion, particularly in the first three months of pregnancy (when 90% of all abortions occur), has an outstanding safety record: the risk of death is 1 in 200,000 and the risk of serious complication, requiring an additional surgical procedure and/or hospitalization, is less than ½ of 1%.

In the United States, more than 90% of all abortions are performed in outpatient facilities, such as doctors' offices and clinics, which are not connected to hospitals. Credit for the outstanding safety record of abortion services is attributed to the specialized care given and received in these facilities. Since the legalization of abortion in 1973, the provision of abortion services in the United States has become a public health model for the rest of the world. There is no evidence that abortions would be safer in another setting, nor that abortions are performed inadequately in outpatient facilities.

Nonetheless, abortion is a political as well as medical issue and states are increasingly inclined to regulate abortion services. It is crucial to separate political issues from health care concerns. There is no justification for politically motivated guidelines that deny women access to abortion services and unjustifiably hinder health care providers. Regulations that codify minimum guidelines for the

provision of quality abortion services are appropriate only to the same extent as for other outpatient medical care.

NAF's guidelines focus on factors that significantly influence the safety of abortion procedures: the experience level of medical professionals, protocols that ensure clean, safe procedures and emergency arrangements in the event of complications. They are designed to be integrated into a general regulatory scheme, not to be cited as support for efforts to single out abortion care for more restrictive regulation. Because abortion is one of the safest of all medical procedures, to do otherwise would only evidence an unjust intent to harass abortion providers and their patients.

EXCERPTS FROM DEFENDANTS' EXHIBIT 18A:
Excerpts from National Abortion Federation:
Standards for Abortion Care (1988)

* * *

NURSING CARE STANDARDS

Objectives

The objectives of abortion nursing services include:

-- The use of the nursing process to assist each patient in reaching her highest level of emotional and physical well-being before, during, and after an abortion;

-- The provision to each patient of basic knowledge about her health so that she may make informed choices regarding her own care;

-- The provision of a safe and health-promoting environment for each patient.

Qualifications of Nursing Staff

The nursing staff includes appropriately trained health workers, including but not limited to licensed professional, practical or vocational nurses.

Each staff person providing nursing care must acknowledge and practice within his/her professional and preparatory limits.

Those responsible for nursing care should be skilled in interpersonal communication. These skills include interviewing, crisis intervention, support and health education. Nurses must exhibit skill in direct patient care, surgical nursing, sterile technique, and the documentation and reporting of these actions.

Each person responsible for nursing functions must understand the basics of reproductive physiology, have a knowledge of contraceptive technology, and have an understanding of the mode of action, adverse effects, and contraindications of medications being dispensed. Each should understand the proper operation and routine maintenance of all medical equipment used. In particular, each must be familiar with the location and proper use of emergency medications and equipment, and must be currently certified to administer cardiopulmonary resuscitation. Knowledge of the emergency protocol and procedure as set forth by the medical director is essential.

A registered nurse or physician should be responsible for supervising assessment of vital signs pre- and postoperatively; assuring availability and proper condition of drugs and instruments; and, if an R.N., discharging recovered patients in consultation with the physician. A nurse may provide direct patient care such as preoperative assessment, cervical dilator insertion, postoperative care, and contraceptive prescription under the supervision of a physician, using written protocols, and in compliance with state and local regulations. A registered nurse must monitor recovering patients until their discharge, if general anesthesia has been used.

Appropriate patient referrals for counseling services should be made by nursing staff, in addition to other members of the health care team, when indicated.

Sensitivity and empathy to the unique needs of each individual patient are essential in abortion nursing care, and professionals should be committed to maintaining a pro-choice, nonjudgmental attitude. They should understand the flow of patients within the facility in order to assure the routine provision of appropriate medical care. They should

be particularly attentive to helping ensure each patient her privacy and dignity.

Those staff members functioning in an expanded nursing role must operate within the limits of written, current, and signed medical orders and/or within written protocols and procedures. They must demonstrate an understanding of the implications of their clinical findings, have direct access to medical consultation, and be supervised by a physician licensed in the state in which the practice occurs.

Supervision of Nursing Care

The person who will perform the abortion must be present in the facility before anesthesia is administered to the patient. Nursing care must be supervised by a registered nurse or physician. This person must be capable of directing the response to emergency situations, and must participate actively as a member of the health care team. A physician must be present in the facility until all patients are recovered and medically discharged.

Training of Nursing Staff

Nursing care providers should be given a training and orientation period appropriate for the level of performance required of each individual. The orientation should include information concerning:

-- preoperative, operative, and postoperative abortion nursing procedures;
-- reproductive anatomy and physiology;
-- sexual health;
-- current contraceptive technology;
-- emergency procedures;
-- patient breathing and relaxation techniques;
-- basic counseling and crisis intervention techniques;

-- working with minors;
-- sterile techniques;
-- documentation and charting;
-- agency policies;
-- professional ethics and legalities;
-- nursing role in the health care team; and
-- stress management!

MEDICAL CARE

Preoperative Care

An adequate preoperative history and physical examination must be conducted, to include:

-- an accurate determination of the duration of gestation;

-- the identification of any preexisting conditions or complications; and

-- the detection of any factors which could influence the choice of procedure, anesthesia, or the pre- and postoperative management.

Testing for pregnancy must be done except when a positive diagnosis of pregnancy has been established by other means such as diagnostic ultrasound. Laboratory procedures to determine anemia (hematocrit or hemoglobin) and Rh factor in every case are mandatory. Other laboratory procedures may be used routinely or selectively. These may include sickle cell testing, endocervical and anal culture for gonorrhea, urinalysis, serologic test for syphilis, chlamydia testing, and cytologic screening for cancer.

* * *

Postoperative Care

The recovery area must be supervised by a licensed nurse or physician who is in the facility. The staff/patient ratio in the recovery area should be appropriate and adequate with regard to the anesthesia used. A physician must remain in the facility until all patients are recovered and medically discharged. In addition, if general anesthesia or intravenous sedation is used, the recovery room must be attended by a registered nurse, at all times, separate from a CRNA who might be giving anesthesia and would therefore be inaccessible.

Prior to discharge, postoperative care should be directed toward confirming that the patient is at minimal risk of serious complications. Periodically, the patient's pulse rate, blood pressure, external bleeding, and general physical condition must be observed by an individual who is trained in the care of postoperative patients. These observations should be made during the postoperative period, the length of which is partly dependent upon the operative procedure employed. Evidence of satisfactory recovery should be noted. If systemic drugs are used for analgesia/anesthesia, the patient must be fully reactive before discharge.

The facility must provide continued contact for an availability of postoperative care on a 24-hour basis by a licensed nurse or a physician.

Appropriate and accessible follow-up abortion care is essential to our patients' well being. Patients must be able to receive medical or counseling care within 24 hours for any problem related to an abortion.

* * *

Equipment and Physical Plant

The facility must have the necessary equipment and oxygen for artificial ventilation and for cardiac and pulmonary resuscitation.

The operating table or conventional gynecologic examining table with accessories must be located in a room of adequate dimension, illumination, and ventilation.

Surgical instruments must be sufficient in number to permit individual sterilization of the instruments used for each procedure and adequate to perform the procedure contemplated. Electrical equipment for vacuum aspiration must be safe and designed to prevent reverse pump action.

The facility must have the capability to transfer a patient immediately to a hospital operating room for emergency care.

Areas in the facility where patient care is given must be accessible to emergency patient evacuation.

* * *

ADMINISTRATIVE PROCEDURE

Personnel Policies and Procedures

* * *

A written job description including an outline of duties and qualifications should be available for each position. The job descriptions should be updated as duties change.

Performance appraisals should be in writing with the supervisors' and employees' signatures. Performance

appraisals should be kept in the employee personnel folder along with other information pertaining to that employee. The employee has the right to review his/her personnel file upon request. The employee also has the right to an interview by his/her supervisor when requested.

* * *

There must be a written and posted protocol for life-threatening medical emergencies. In addition there must be written descriptions of procedures and policies in each area of care, including:

-- nursing
-- counseling
-- abortion procedures
-- laboratory services

It is recommended that clinic hours be set considering the needs of the patients as well as the staff.

* * *

Confidentiality

Every woman has the right to expect her privacy will be respected and confidentiality of her records protected. Since most states do not have legislation protecting the confidentiality of medical records, care should be taken when making a notation on her record (particularly counseling notes). In addition, if a member of the facility receives a subpoena for a woman's records, action must be taken to prohibit the release of the records without the woman's consent.

Additional suggestions to protect confidentiality are:

-- keep all doors locked in accordance with fire code except the door where the patients enter;

-- before discarding, shred all waste paper that may have a patient's name or information;

-- each night, lock all information with patients' names, including appointment books and daily logs;

-- keep any and all paperwork with identifying names and numbers in desks -- not unattended in full view of others in the clinic; and,

-- never disclose to a telephone caller information about a patient that may be in the facility, rather state that if that person is in the facility you will deliver a message to have the patient return the call.

* * *

Administrative Supervision

While direct professional supervision of physicians, nurses, and counselors is the responsibility of the senior professional in each area, the chief administrative officer responsible for the general supervision of clinic functions should assure that personnel policies and procedures are formulated, distributed, and observed in an equitable manner.

In a professional organization such as an abortion service, this includes the arrangements for continuing training in the form of individual supervision, in-service education programs, and continuing education opportunities for all professional and paraprofessional staff members.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
TERRY L. BUFFKIN
JULY 13, 1998

[BUFFKIN - DIRECT 45]

Q. Pardon me?
A. In the first trimester you do the suction and curettage,up to fourteen menstrual weeks.
Q. And do you know approximately what the incidence of complications is with the suction curettage abortion procedure?
A. The overall total complication rate is going to be about one in a hundred. When you talk about things of a serious nature requiring a hospitalization, you're going to be looking at more in the one in two thousand type range. If you talk about the ultimate complication, the mortality of the procedure, once a woman becomes pregnant and if she has a first trimester abortion, she has a risk of less than one in a hundred thousand of dying. Should a woman not have an abortion or miscarriage and carry the pregnancy to term, just from a purely complication standpoint, her risk of dying from a delivery of a full term pregnancy is about twenty-five times higher than that. So pregnancy is just the earlier, the less complications; the further along, the more.
Q. And based on your experience providing abortions and

as a physician, do you have a sense of how the level of risk involved with first trimester suction curettage procedures compares to the safety of other surgical procedures?

[BUFFKIN - DIRECT 46]

A. Well, the things you read will say it's the safest surgical procedure you can perform.
Q. In light of your experience as a physician, do you believe that to be true?
A. I believe that to be true.

* * *

[BUFFKIN - DIRECT 47]

Q. Oh. I was asking if you could explain the types of complications that might arise after the procedure.
A. Okay. The most common complication that we see is after the procedure is done, patients will bleed like a period. Occasionally, instead of the blood coming out of the uterus, the blood will just sort of collect in the uterus. And that will usually happen a day or two after the procedure and you'll get a phone call that the patient is running a low grade fever, cramping more than they usually do and maybe bleeding heavier than a period. So you'll see that patient back.
And usually when you do your examination the uterus feels a little tender, a little bit enlarged. Usually you can just do an ultrasound at that point and see if there is retained clots or possibly retained tissue. When you do the ultrasound, you really can't tell which. Depending on the patient, you can do one of two things; you can place the patient on an oral antibiotic and give them a

23 medication. It's called ergotrate or methergine. And what
24 this medication does is it causes the uterus to contract.
25 And when the uterus contracts, it has the ability to push

[BUFFKIN - DIRECT 48]

1 out clots. So you give the patient the medication and see
2 them back one or two days later.
3 The other option is if the uterus is obviously
4 enlarged, very tender, you do the ultrasound and there is a
5 lot of clots in there, the fever, maybe it's more than a
6 hundred, like it might be 101 or higher, then in that case
7 you would at that point go ahead and actually do the
8 procedure over again, do the same thing, the same suction
9 curettage and get out the clots. And like I said,
10 occasionally there can be tissue in that, so you examine it
11 to see if it's just clots or tissue. That's the most
12 common thing we see.
13 Q. Can I ask you a question about that. You've talked
14 about two different ways that you can respond to that
15 problem; is that correct?
16 A. Correct.
17 Q. Can you provide that care in your office, both kinds
18 of care that you just described?
19 A. Yes.
20 Q. And can the patient get up and leave the same day?
21 A. Yes.
22 Q. Go on. Are there other complications?
23 A. Well, when you're doing the procedure, you -- we can
24 start with the difference in the anesthesia. The rates of
25 complications between the local and the IV sedation, the

[BUFFKIN - DIRECT 49]

1 rates of complications are the same, but there is a
2 difference in the complications. Patients under local will

tend to have more problems with fever, they will have more problems with a fainting type reaction. It's called a vasovagal response, where they'll feel faint. The patients undergoing the general will have more problems with cervical tears, which I'll talk about, and actually with -- and with perforating the uterus. The two anesthetics have differences in mortality. You know, nothing is without risk. About three women per million have the possibility of dying from a local anesthetic reaction, and about five per million have the possibility from the sedation that we use. So there is some differences there. When you get to the procedure itself, we talked about placing that tenaculum on the cervix. And the tenaculum is used to hold the cervix steady. And it's possible for it to slip off. And if it slips off, it's going to -- it can tear the tissue. And if it bleeds, then you sometimes have to put a stitch in it. But most of the time it doesn't bleed and you don't have to do anything.

Q. If it bled, when would you know it was bleeding?

A. You would be able to visualize it at the time it slipped off.

Q. And if you had to do a stitch, when would you do that?

[BUFFKIN - DIRECT 50]

A. At the same sitting. Before you completed the procedure, you would know if it needed a stitch. When you're -- once you put the tenacula on, once you measure the uterus, we use something called a sound -- but, again, it's just a thin metal rod. And it's possible, when measuring, to actually pass it through the wall of the uterus. And that's called a perforation. And if a

perforation occurs in the middle, in the midline, then it basically is of no consequence. And then those thin metal dilators that we talked about, it's possible to put those through the wall of the uterus. And as long as it's in the midline, those generally have no consequences.
Q. What does that mean, the midline?
A. Well, the uterus -- we can kind of visualize if this was the uterus (indicating), there's -- the blood supply comes in from the sides. The actual arteries and veins come in from the side. And if we sort of pretend that this is the cervix here, so when I'm passing anything into the uterus, I always want to stay in the middle. I never want to go to the side because that's where you could get serious hemorrhage. So if you perforate the wall of the uterus with a sound or a dilator and recognize it and remove it, it's not going to create any consequence.
Q. Why does it create no consequence?
A. Well, once the uterus is empty -- the uterus is a

[BUFFKIN - DIRECT 51]

muscle and the uterus contracts down. So just in the normal muscle contraction, it closes the hole so the hole no longer exists. So it doesn't create any problem.
Q. So if you unintentionally cause a puncture within the midline, does the patient need any kind of medical attention?
A. Well, what you do -- the key is if you can get the uterus empty. Okay? If you can -- you know, you're putting these instruments in a canal. And if you can get the instruments in the canal, into the uterus, you can get the uterus empty at that sitting, then the perforation has no consequence. If you perforate and you're unable to do that, then -- and these patients will be stable -- you would transfer that patient to the hospital. And then you would use the laparoscope, which is the telescope you put

in your bellybutton. And you can look in with the laparoscope and then work from below and you can get the uterus emptied and you can observe if there is any damage.
But with midline punctures you're not really concerned about damage to internal organs.
Q. Are there any other complications from the suction curettage procedure?
A. Well, like with any surgery, there is always the chance of bleeding excessively and the chance of infection.
And they're not common, but they do occur.

[BUFFKIN - DIRECT 52]

Q. If either of those occurs, what kind of medical treatment does the patient require?
A. Usually if the patient bleeds excessively, the most common reason is the uterus, the muscle, has not sufficiently contracted down to stop the bleeding. The uterus stops bleeding by muscle contraction. It's different than cutting your hand. If you cut your hand, you have to have clotting factors to stop bleeding, but the uterus is different. It's unique. It must contract. So if you have hemorrhage and the uterus is not contracted, there are medications that you can use to make the uterus contract and stop the hemorrhage.
Q. Can you give those medications out of your office?
A. Yes.
Q. How would you know if a patient was experiencing that complication?
A. You would observe the bleeding at the time of the procedure being excessive.
Q. So this is usually something you'd know about before the patient has left?

A. Right.
Q. In your experience, how often does a patient need to be hospitalized as a result of a complication arising out of a first trimester suction curettage procedure?
A. We have once -- it's usually about once every two

[BUFFKIN - DIRECT 53]

years. And I would do, you know, over a thousand procedures per year. So I would say one out of two thousand. And the most common cause would be that, bleeding excessively.
Q. In your opinion, in what types of medical facilities can first trimester suction curettage abortions be safely performed?
A. Well, they can certainly be safely performed in a doctor's office. If there is a clinic and the abortion is done by a qualified physician, it can be done in a clinic. And then certainly the ambulatory surgical facilities would be fine and hospitals would be fine, just expensive.
Q. Can you describe just generally what is the difference between those four settings that you have just described?
A. Well, relative to the -- well, just in general, doctors' offices and freestanding clinics or like any other doctor's office type setting -- once you get to an ambulatory surgical center, patients in there are generally going to be healthy, they're just going to be having more invasive type procedures than you would want to do in the office. For instance, we would do -- say if a woman wanted to have a tubal ligation, and that's something we use the laparoscope for, we tend to do that in an ambulatory care facility. Hospitals are obviously for complicated procedures, but they're also for patients who have other

[BUFFKIN - DIRECT 54]

medical problems. So you might, on occasion, do a fairly simple surgical procedure in a hospital if say a patient had a heart disease or other significant medical problems.

* * *

[BUFFKIN - DIRECT 70]

Q. I'd like to just use an example to give the court an idea of how this works. You talked before about the tests that you give to your abortion patients. You talked about Rh, I believe, and some other tests. Do you test all of your patients -- all of your abortion patients for chlamydia and gonorrhea?
A. No.
Q. Why don't you test them all?
A. Well, it's not indicated in the vast majority of the patients. You only test for chlamydia and gonorrhea in high risk patients, those patients who have multiple sexual partners, a promiscuous lifestyle. The other time you would test it is if a patient is exhibiting symptoms,

[BUFFKIN - DIRECT 71]

they're having an abnormal discharge from their cervix or you detect some low grade fever and some tenderness in their cervical or uterine area. You do the test, but you do it when it's indicated because the vast majority of the patients just don't need it.
Q. What is wrong with doing the test even if it's not indicated, just to be sure? Is there anything wrong with that?
A. Well, there is. It's wrong to make people pay for things that they don't need because they don't come free.

There is a charge for any testing that's done. And you just want to avoid unnecessary charges for a patient.
Q. Do you consider that kind of issue in any other areas of your practice?
A. Always. I mean it's an issue every time you see a patient. If you see a patient, for instance, who may be having some pain in her lower abdomen and she's never had intercourse, that would automatically rule out sexually transmitted diseases. It would rule out even abnormalities of her pap smear because you don't see those in women who are not sexually active. So it would point you in the direction of an ovarian cyst or a problem with the bladder or the rectum. So every time you see a patient, you're using those judgments and you want to test when necessary, but certainly don't want to just test.

* * *

[BUFFKIN - DIRECT 83]

Q. Do you have any opinion as to how an increase in the cost of an abortion will affect the health of women seeking abortions?
A. Well, if you increase the cost, certainly -- you know, I see one or two things happening. There's going to be certain patients that price will be a difference and it may affect their ability to obtain an abortion. The second thing, it could affect -- you know, a patient who just doesn't quite have enough funds may decide to wait, you know, a week or two to come in. And pregnancy is real straight forward. There is no mystery. The earlier you are in your pregnancy, the safer everything is. A first

trimester abortion is safer than a second trimester abortion. Delivery of a full term pregnancy is the most

[BUFFKIN - DIRECT 84]

dangerous thing that can occur. So pregnancy is related to gestation. So your price goes up, some people just can't do it, other people are going to delay. And that's just going to increase risk for them.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
WILLIAM L. LYNN
JULY 14, 1998

[LYNN - DIRECT 248]

Q. And if you are required to comply with the regulations as set forth in 61-12 and you have new costs associated with compliance with those regulations, what do you anticipate you would do as a result of having those additional costs?
A. The only reasonable thing that I can see would be to

[LYNN - DIRECT 249]

pass the costs on to the patients.
Q. Do you anticipate then that you would have to charge more for an abortion procedure to your patients?
A. Yes, I do.
Q. In addition, do you believe you would have to absorb some of those costs?
A. It seems likely. Because you can only raise your fees so high, but I don't know that I could absorb any of the costs.
Q. And if you did have to absorb costs or if the number of patients dropped off because of the need to raise fees, do you believe you would be able to stay in business at the two facilities?
A. I think it would be very difficult to do, if not

15 impossible.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
STEVEN J. FASS
JULY 14, 1998

[FASS - DIRECT 332]

Q. Thank you. Could you try to list for me the surgical procedures that you perform within the office setting?

[FASS - DIRECT 333]

A. There are all kinds of procedures, basically minor skin moles and lesions; subcutaneous lesions; sebaceous cysts, for instance; lipomas, occasionally large ones; removal of various implanted ports and lines, catheters that may have been used for chemotherapy or for dialysis; minor breast biopsies that are relatively superficial; debridement of skin ulcers or pressure sores; occasionally even removal of toes in the office setting, a patient that may be relatively anesthetic already due to diabetes or some other kind of physical condition that renders them less sensitive so we can do that. That is about all I can think of at the moment.

* * *

[FASS - DIRECT 337]

Q. What types of complications can arise during these office surgical procedures that you've described?

25 A. In general, as with any kind of surgery, infection is

[FASS - DIRECT 338]

1 a concern, bleeding is a potential complication. The
2 patient comes in with various medical conditions of their
3 own which can complicate things. Perhaps the patient is a
4 diabetic who has taken their insulin and their glucose
5 level may bottom out. They can faint just from a vasovagal
6 reaction just because they're afraid of the procedure and
7 they're nervous. With other procedures, like just removing
8 a mass, there is always a risk of retaining or leaving a
9 section of that mass in place which could then go on to
10 grow further and further complicate or become infected.
11 And generally those are the concerns.
12 Q. Is there any risk that you will, by doing the
13 procedure, harm the patient by the steps that you take?
14 A. There is always a concern whenever you remove anything
15 that you could potentially harm adjacent structures in the
16 process, depending on where the structure is that you're
17 dealing with. And that's something that has to be
18 discussed with the patient up front as a potential
19 complication.
20 Q. Have you seen any of these types of complications in
21 your practice, have you seen them occur?
22 A. In the office setting, fortunately they're not
23 frequent, but I have seen some. I recall an incidence of a
24 breast biopsy that was done in the office where a patient
25 had evidently very large blood vessels in the region,

[FASS - DIRECT 339]

larger than were anticipated. And this required eventually packing the patient with gauze and transferring them over to the hospital where we in turn put them to sleep. And with better equipment and better lighting, et cetera, we could complete the procedure and stop the bleeding. Another incidence that I recall is in debriding an infected wound on an abdomen in a woman that had a hernia repaired. Sometimes the suture material, even though it breaks down on its own, can be retained for a period of time and harbor bacteria. In opening that wound up and debriding down at the base at the level of fascia, which is the closure level, actually there was a biopsy done of or an incision made into underlying bowel. That was recognized at the time and she again had to be transferred to the hospital setting and had to undergo general anesthesia to have that bowel repaired at that time.

Q. So there was an accidental injury to the bowel by instruments?

A. Correct.

Q. And have you seen infection occur after any procedures?

A. Of course.

Q. Why do you perform surgeries in your office?

A. There are a host of reasons. Generally it's easier

[FASS - DIRECT 340]

for the patient. If they don't have to go through the period of preparation and reversible medications after surgery, it's much shorter. The cost is tremendously less. Usually it's more comforting to the patient if it's done in the office setting, therefore it's not a big deal, it's not

a major surgery and they don't get as hyped up and worried about it. It takes less time for them. There are even some insurance companies that try to direct some of these procedures to an office setting by promising higher compensation as an incentive. Generally we do it because it's what the patient wants and it's a lot less expensive for them.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
THOMAS WILLIAM CAMPBELL, JR.
JULY 14, 1998

[CAMPBELL - DIRECT 366]

Q. Your Honor, I'm sure you have a copy. Do you have an opinion as to whether Regulation 61-12 will affect the cost of providing abortions?
A. I think it will increase the price of abortions. I think any time you add regulations to any kind of industry, profession, et cetera, it drives the costs up because you've got to add a layer of bureaucracy to review the people that are being regulated. And it mandates obviously time to comply with these regulations, plus any changes that you have to make.
Q. Do you have an opinion as to whether that regulation will affect people seeking abortions?
A. It certainly could. Because anything that increases

[CAMPBELL - DIRECT 367]

the price of abortion procedures will decrease the availability to the general public.

* * *

[CAMPBELL - DIRECT 388]

Q. Have you ever had situations where somebody's inability to pay caused them not to be able to get an

[CAMPBELL - DIRECT 389]

abortion at all?
A. Many times.
Q. Is that because they exceeded the fourteen-week period?
A. Exactly.
Q. And if a person was unable to obtain that abortion because they couldn't afford it at that time, did their risk of complications go up?
A. If they -- yes. Because pregnancy is much more dangerous than having an abortion procedure. And a second trimester abortion is more dangerous than a first trimester abortion.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
LORRAINE D. MAGUIRE
JULY 15, 1998

[MAGUIRE - DIRECT 486]

Q. And do you have, based on your experience at your clinic, any understanding as to how additional price increases beyond what's already required in operating your business, how that might affect patients seeking your services?
A. We see women now that have problems coming up with the fees that we charge. And to go higher, possibly considerably higher, would certainly price abortion out of the reach of some women.
Q. And what is that belief based on?
A. Just what I see on a day-to-day working in the clinic with the hardships that people have coming up with the fees that we charge now.
Q. And if you have to raise your cost of providing abortions by somewhere in the range of thirty to fifty dollars, do you think that would price abortion out of the range of the ability of some of the women who would otherwise seek services at your clinic?
A. I think that it would, number one, make women have to

wait longer to come up with the money, which could possibly put them beyond the first trimester abortion level and then require her to go, if she could afford it, out of state to seek abortion services for second trimester abortions. I think that some women would be forced to continue a pregnancy that for whatever reason they feel they can't continue. And then it concerns me that some women that can't come up with the fees to pay for first trimester abortion and can't possibly come up with the fees for a second trimester abortion will end up trying to abort themselves.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
LINDA O. MORPHIS
JULY 15, 1998

[MORPHIS - DIRECT 556]

Q. And, in particular, have you read section 205.D, which
requires that an RN supervise nursing care in a facility
that provides first trimester abortions?
A. Yes.
Q. Do you have an opinion of that requirement?
A. I do have an opinion. After reading the regulation
several times, it seems to me that it is an unnecessary
requirement.
Q. The RN requirement you're speaking of?
A. Yes.
Q. And, in your opinion, why is that requirement
unnecessary?
A. I don't feel that the nursing care that's provided
during the procedure, prior to the procedure and afterward
necessitates an RN be present.

* * *

[MORPHIS - DIRECT 557]

Q. Okay. And, again, if we're talking about a facility
in which the physician is supervising the nursing care, is

there going to be a difference between what an RN can do
and what a medical assistant who has been trained on the job can do in terms of providing nursing care?
A. None other than those that I just mentioned.
Q. The IV medication?
A. Right.

* * *

[MORPHIS - REDIRECT 572]

Q. Let me just ask you one last question about the RN requirement. Well, actually it's about LPNs. To the best of your knowledge, is it within the permissible scope of an
LPN's practice to observe the recovery of an abortion patient when the physician who supervises nursing care is in the same facility as that LPN?

[MORPHIS - REDIRECT 573]

A. Absolutely.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
ALAN SAMUELS
JULY 15, 1998

[SAMUELS - DIRECT 629]

Q. So in drafting these regulations, you say many of the provisions were simply provisions you've applied to other types of facilities and they had nothing to do specifically with a problem associated with abortion facilities.
A. True.

* * *

[SAMUELS - DIRECT 634]

Q. Did you in reviewing -- well, in drafting and reviewing the regulation, were any of the provisions based on a desire to protect potential life? Was that one of the goals in drafting this regulation?
A. To protect ---
Q. The potential life of the fetus. Was that a goal, as you understood it, for these regulations?
A. Not in my mind.
Q. Do you know if Mr. Moore or anyone -- to your knowledge, did anyone working on these regulations under

your supervision have that as one of their goals?
A. Not to my knowledge.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
DAVID A. GRIMES
JULY 16, 1998

[GRIMES - DIRECT 714]

Q. Okay. You referred to the American College. Do they
publish guidelines in this area?
A. Yes, they do.
Q. Is the most recent edition of those the Guidelines for Women's Health Care?
A. From 1996, I believe, is the most recent one.
Q. Who writes those guidelines for ACOG?
A. A committee of members of the college will write it and then it gets extensive review before it's sent out with the imprimatur of the college on it.
Q. In your opinion, what is the significance of those guidelines in the field of obstetrics and gynecology?
A. They provide our best current assessment as to what is
appropriate care. It defines broadly general guidelines. It doesn't restrict a doctor to those, but suggests this is in general a workable approach.

* * *

[GRIMES - DIRECT 718]

Q. Do you know what the safety of that procedure is?
A. As I said before, we know a great deal about it

because it's been such a common operation and so thoroughly studied. It's one of the safest operations in the contemporary practice of medicine. By comparison, having a first trimester suction curettage abortion is safer than having a shot of penicillin in a doctor's office.
Q. How does a first trimester suction curettage abortion compare in terms of risks, complications and invasiveness to other OB/GYN surgeries performed in a doctor's office?
A. It's comparable or safer. For example, it's very analogous to office D&C, dilation and curettage, which has been practiced in offices in this country at least for seventy years. It's similar to hysteroscopy, a procedure in which we put a tiny telescope in through the cervix to look inside the uterus. It's similar to other kinds of procedures such as that.

[GRIMES - DIRECT 719]

Q. How does it compare in terms of similar risks and complications to other non-OB/GYN surgical procedures performed in doctors' offices?
A. Well, it's as safe or safer than many of these, such as colonoscopy, which is looking inside the bowel with a telescope or a sigmoidoscopy is similar or other sorts of invasive procedures such as a bone marrow aspiration.
Q. Could you briefly describe the procedure that is used in performing a medical abortion.
A. There are several ways of accomplishing medical abortion. In four countries in this world there are licensed providers of mifepristone, which is an antiprogestin agent. With that approach one receives mifepristone, two hundred milligrams to six hundred

milligrams commonly. The woman then returns in two days and receives a prostaglandin drug by mouth or by vagina, which then induces a medical miscarriage. In the U.S. we do not yet have mifepristone on the market, so some clinicians have used, as an alternative, a drug called methotrexate, which is a cancer chemotherapy drug. It can also be used in conjunction with the prostaglandin called misoprostol.

Q. And how is that administered, either drug?

A. The methotrexate is given as an intramuscular injection and the misoprostol can be given as pills by

[GRIMES - DIRECT 720]

mouth or in the vagina.

Q. And then once the injection is done, is the procedure over for the patient?

A. No. She then has a spontaneous miscarriage, if you will, induced by these drugs. It's much like a miscarriage.

Q. Does that happen in the physician's office?

A. It depends. A substantial portion of women will pass the embryo within four hours after receiving the misoprostol. That can take place either at home or, if the woman prefers, in the clinic or office.

Q. How does a medical abortion compare in terms of risk and complications to other OB/GYN procedures performed in the physician's office?

A. There have been no direct comparisons, to my knowledge, comparing to other OB/GYN office procedures. We

can say, however, that medical and surgical abortion early
in pregnancy are both very safe.
Q. In your opinion, in what types of facilities can first trimester abortion procedures be safely performed?
A. Virtually any facility.
Q. Would that include a doctor's office?
A. Absolutely.
Q. And would it include a private clinic?
A. Certainly. Indeed, what was shown by studies that my

[GRIMES - DIRECT 721]

colleagues and I did twenty years ago was that it's safer to have an abortion -- a first trimester abortion done outside of a hospital than in a hospital. That paradoxical situation remains.
Q. Why is that?
A. It's a function of the type of patient. Patients who have preexisting medical illnesses will gravitate toward hospitals. And also the more skilled providers are in the clinics. Doctors in hospitals tend not to do many abortions in contrast to doctors in clinics and offices. And doctors are like other people, we tend to do well what
we do often.
Q. So more experienced providers, in your opinion, provide safer abortions?
A. Clearly. There is clearly a learning curve with this surgery as with any other surgery.
Q. Do you know what ACOG's position is regarding the question of whether first trimester abortions can be safely performed in doctors' offices and clinics?
A. Yes, they have an opinion.
Q. What is that opinion?
A. That it's safe and appropriate.

Q. Is that position documented in any of ACOG's publications to your knowledge?
A. Yes, it is.

[GRIMES - DIRECT 722]

Q. Which publications?
A. Well, it's in this one, which is plaintiff's exhibit sixteen, entitled Guidelines for Women's Health Care.
Q. If you can find it quickly, can you point me to where in there you believe that opinion is set forth?
A. It's on page one twenty-nine where it says, and I quote, "Abortion may be performed in a physician's office, an outpatient clinic, a free-standing ambulatory surgical facility or a hospital." End of quote.

* * *

Q. Are you aware of any public health problem with abortions in South Carolina at this time or over the past few years?
A. Not at all.
Q. And would you have any basis for knowing of such a problem if one existed or had existed recently?
A. Yes.
Q. Why would you know about it?
A. Through contacts with my colleagues at the CDC, through contacts with colleagues in the field and I now

[GRIMES - DIRECT 723]

practice in an adjacent state.
Q. I would like to give you what's been marked as plaintiff's exhibit ten. I believe it may be in front of you from the last witness. Have you seen that document before?

A. Yes, I have.
Q. Have you had a chance to review it?
A. I have.
Q. Have you formed any opinions as to the affect that that regulation will have on the women of South Carolina who -- on women who seek abortions in South Carolina?
A. Yes, I have.
Q. And in your opinion, is that regulation likely to further the health of women who seek abortions in South Carolina?
A. No. This document, if enacted, will hurt the health of women in South Carolina.
Q. Why is that?
A. The document is ill-conceived, poorly crafted, ambiguous and medically naive. It's also biologically naive.

* * *

[GRIMES - DIRECT 726]

Q. Are you familiar with the various requirements in that regulation that require written policies and procedures of various types, such as patient rights, quality improvement and operating procedures?
A. Yes, I'm familiar with them.
Q. Do you have an opinion as to those types of administrative requirements?
A. They're unnecessary in an office or a small clinic. They're more appropriate for a large general hospital.
Q. What do you think the effect of the imposition of those types of administrative requirements would be on the health of women seeking abortions in South Carolina?
A. It's expensive. It's expensive in terms of clinic and

[GRIMES - DIRECT 727]

provider time, in terms of compliance, documentation updating. And all that is time taken aware from taking care of patients, which is what we're about.
Q. In your opinion, would that be time well spent, time justified by benefits?
A. None. And the cost will be reflected in patient fees.
Q. And what will the effect of that be in your opinion?
A. It will help to drive the cost of this operation out of the reach of many women who desperately need this for medical and other reasons, so it will have a paradoxical effect. These regulations ostensibly proposed to improve health will hurt health in South Carolina.

* * *

[GRIMES - DIRECT 728]

Q. In your opinion, it's not good public health practice to require that all abortion patients undergo those tests?
A. Not at all. Chlamydia, for example, is a disease of young women, teenagers especially. And for women over the age of twenty-five to have chlamydia is extremely unlikely unless they've had a new sexual partner. So one should target screening activities for patients at risk. Let me give you an example. It makes no sense to do cervical cancer screening with pap smears for nuns. This is a disease that's transmitted by sexual intercourse. So people that don't have sex shouldn't be having pap smears. It would be a waste of resources.
Q. In your opinion, who is in the best position to determine what tests would be appropriate for particular

patients?
A. The doctor in conjunction with the patient. That should be a dual decision.
Q. Are you also familiar, Dr. Grimes, with various physical plant requirements in Regulation 61-12, such as air flow requirements, air exchange specifications and requirements as to the maintenance of the interior and exterior of the facility?
A. Yes, I am.

[GRIMES - DIRECT 729]

Q. Do you have an opinion as to those types of requirements?
A. They range from burdensome to humorous.
Q. Do you think they will improve the health of women seeking abortions in South Carolina?
A. No. But it might have some effect on the insect population of South Carolina.
Q. Do you think that those requirements have benefits that could possibly outweigh their costs?
A. Not in my estimation, no, ma'am.

* * *

Q. May I have one moment, Your Honor. Dr. Grimes, I'd like to just discuss a couple more sections with you. As I

[GRIMES - DIRECT 730]

said, I promise not to go through every section. But let's talk about a couple of physical plant requirements. You're familiar with the requirements as to air flow directions and air exchange rates?
A. Yes, I am.

Q. What is your opinion on those?
A. Unnecessary and burdensome.
Q. Why are they unnecessary in an abortion facility?
A. To require, for example, ten air exchanges per hour in a dirty laundry room has no relevance on patient safety.
Q. What about requiring a specific number of air exchanges in the procedure room?
A. That also is unrelated to patient safety; whereas it has relevance in a general hospital where there may be respiratory pathogens or germs that are being aerosolized, put in the atmosphere, it may have relevance when you have an open wound. But that's not relevant to this operation which involves no incision, no cutting, no exposure to the outside atmosphere.
Q. So that is not relevant to the performance of first trimester abortion?
A. Correct. Nor has it ever been shown in any study to have any impact on the safety of the operation.

* * *

[GRIMES - DIRECT 731]

Q. And have you looked at the provisions in this regulation that require specific staff meetings? For example, that clinical staff meet four times a year in sort of a formal manner and maintain minutes of their meetings, are you familiar with those?
A. Yes, I am.
Q. Do you have an opinion on those?
A. These look like boilerplate language that was lifted from a general hospital and then plunked down here in an office or clinic. They're appropriate for hospital staffs, but not for a private office. Indeed, in my experience when in private practice, we did not have such meetings.

Q. Why are they not appropriate in private practice?
A. They're cumbersome, unnecessary and take physicians away from the business of taking care of patients.

* * *

[GRIMES - DIRECT 732]

Q. And is there any good reason why a patient who has just undergone a first trimester abortion procedure could not be adequately recovered in the room in which she had the procedure?
A. No. And that's commonly done.

* * *

[GRIMES - DIRECT 733]

Q. What is the harm to women if the cost of abortions is driven up?
A. It will place it out of reach of many poor women. And that's already a problem for women in rural parts of South Carolina, indeed rural parts of America. Access to abortion services, which can be lifesaving, are often limited by transportation and costs. To make it further inaccessible will have a direct negative effect on the health of women.
Q. And if a woman waits until later in her pregnancy to have an abortion -- not from the first trimester, but let's say she's eight weeks pregnant and she needs to wait a couple of weeks before she undergoes an abortion. Is there any problem with her doing that?
A. One of the most important lessons we learned at the

CDC twenty years ago was that delays in abortion care of any source, administrative, financial, transportation, all have the same net effect; they drive up the risk of complications and of death. So delays are to be avoided.
Q. And in your opinion, does the price of an abortion have any bearing on whether a woman delays obtaining abortion?
A. Absolutely. And this has been extremely important in

[GRIMES - CROSS 734]

the U.S. since August of 1977, when the Hyatt Amendment went into effect, depriving poor women of Medicaid support for their procedures. Since then, women have had to scramble to get the money together. And this oftentimes delays them weeks, if not months, before they can gather the money to pay for the procedure.

* * *

[GRIMES - CROSS 746]

Q. Doctor, would you agree that by not screening for chlamydia, we might have to spend a lot of money for complications concerning an unrecognized disease?
A. No, sir. You're mixing apples and oranges here. These regulations deal with abortion practice, not screening and management of sexually transmitted diseases nor tuberculosis. That's my concern as both a gynecologist and as a public health physician.
Q. Well, doctor, doesn't ---
A. What we're doing here, sir, is bundling health care services that don't need to be bundled. I bought a

computer last year that had all kinds of software I didn't want on it. I had to pay for that. Women, likewise, shouldn't pay for services they don't want and don't necessarily need. We should target the screening services for the individual woman and her risk.

* * *

[GRIMES - REDIRECT 756]

Q. (By Ms. Jones) Dr. Grimes, the ACOG Guidelines for Women's Health Care that we've been talking about, in your opinion, are those guidelines or requirements or something else?

A. They are as their name implies, guidelines. They're suggestions. They're not standards. And one may use them or not use them as one sees fit.

Q. And the NAF standards, are those guidelines or requirements?

A. NAF standards are as the name implies, standards. And they indeed underline text that must be adhered to, others are suggested.

Q. And who must adhere to the underlined text?

A. Members of NAF to maintain their good standing with the organization.

Q. And Regulation 61-12, at issue in this case, in your opinion, are those guidelines or requirements?

A. My interpretation is they're requirements. But in

many places they're so vague as to be unenforceable because they're uninterpretable.
Q. What is the difference between a guideline and a requirement?
A. A requirement is something that must be done. A guideline is something that may be done, as I understand it.
MR. OXNER: Your Honor, I don't think this is responsive.
THE COURT: Well, I think I understand the difference without the need for testimony.
REDIRECT EXAMINATION RESUMED BY MS. JONES:
Q. And, Dr. Grimes, if you believe that something is a good guideline for physicians, does that mean that you think it is a good requirement for physicians?
A. No, I would not.
Q. And do you, Dr. Grimes, think that any of the requirements in Regulation 61-12 are going to further the health of women seeking abortions in South Carolina?
A. Clearly not.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
WILLIAM R. LAFFERTY
JULY 16, 1998

[LAFFERTY - DIRECT 780]

Q. And in that regard, your regulations could not have possibly been promulgated for the purpose of protecting the existing health, safety and welfare of women seeking a first trimester abortion.
A. I think it needs to be made clear a statement I made before the break.
Q. Answer that question for me first and then I'll let you explain it.
A. The answer to your question specific to abortions, no. But the answer, as I mentioned before the break, is that my orientation in the drawing up of the construction requirements was not directed toward abortion clinics and many of your questions specifically addressed that. I was looking at a business occupancy, physician's office, clinic that performs minor procedures. Abortion wasn't even in that definition.
Q. So there would not have been any way that you could have been specifically looking to protect or insure the health, safety and welfare of women seeking abortions in South Carolina when you prepared your regs.
A. That was not my orientation.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
GEORGE MOORE
JULY 16, 1998

[MOORE - DIRECT 838]

Q. What I asked was did you include some of the requirements in Regulation 61-12 on the grounds that they were standard requirements that DHEC hoped or intended to include in all of its regulations of all kinds of facilities?
A. And my answer was correct. For example, licensing requirements.
Q. I believe you spoke of the penalties earlier also. Was that a similar situation?
A. The penalties. The TB requirements are becoming fairly consistent now, that type of information.
Q. Is it one of DHEC's goals at this point to try to make the regulations somewhat -- I don't want to use the word generic -- but standardized?
A. Very much so.
Q. So you wanted to put some things in Regulation 61-12 so that Regulation 61-12 would look like all your other regs; is that accurate?
A. Well, within certain limits, yes.

[MOORE - DIRECT 839]

Q. Right. And when you did that, did you assess whether those sort of generic sections would further the health of women seeking abortions?
A. I don't think so.
Q. And when you decided to include those standardized requirements, did you make an assessment each time that first trimester abortions were comparable to the procedures performed in the other kinds of facilities that DHEC regulates?
A. Again, I'm not sure I understand your question. Comparable to?
Q. Yes. In terms of risks, safety, invasiveness.
A. Well, it certainly could have been on a par -- reasonable par with ambulatory surgery as far as invasive procedures, yes.
Q. Do you think first trimester abortions are comparable to the procedures performed in ambulatory surgery facilities?
A. I would assume -- and I'm certainly not a medical expert, I would assume that there are procedures in both of those facilities that are comparable.
Q. Let me go back. When you decided to put standardized sections into Regulation 61-12, did you make a determination at that time that that was appropriate because first trimester abortions were comparable to the

[MOORE - DIRECT 840]

procedures performed in other facilities that you regulate?
A. No. I don't think that was being considered at that

time. We tried to put common standards that would apply to
all facilities.
Q. And as we've just heard, I believe it's fair to say that Mr. Lafferty was primarily responsible for drafting the design and construction requirements.
A. That's correct.
Q. Mr. Lafferty is not a doctor of course, right?
A. That's correct.
Q. Not a medical doctor at least. And he doesn't have any experience with the provision of abortions, does he, to
your knowledge?
A. Not to my knowledge.

* * *

[MOORE - DIRECT 843]

Q. I'm going to hand you what's been marked as plaintiff's exhibit twenty-six. Do you know what this document is?
A. Yes.
Q. What is it?
A. It is a letter that came from ACOG to me from one of the attorneys there.
Q. Do you recollect receiving this letter?
A. Yes.

* * *

[MOORE - DIRECT 845]

Q. Thank you. Did you ever contact Ann Allen or the American College of Obstetricians and Gynecologists regarding the comments in this letter?
A. I don't recall. I don't really think that I did.

* * *

Q. Fair enough. It was a while ago. Would it be fair to say that you did not base any of the requirements of this regulation on the state's interest in the potential life of the fetus?
A. Repeat your question, please.
Q. I'm asking whether you based any of the requirements of the regulation not on an interest in the health and well-being of the mother, but on a state interest in the potential life of the fetus?
A. Well, I believe that there is a viability definition in there and a medical emergency definition which relate to that somewhat. But as far as what you have said, no, it was not.
Q. Apart from the two definitions you just spoke of, are any of the other requirements -- are any of the

[MOORE - DIRECT 846]

requirements, since those aren't requirements, are any of the requirements in the regulation directed towards furthering the state's interest in the potential life of a fetus?
A. I don't believe so.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM TESTIMONY OF
CHARLES J. WARD
JULY 17, 1998

[WARD - CROSS 1122]

Q. Is it your position that even aside from this regulation at issue in this case, that there already exists definite rules and regulations that cover what one should provide when one is doing a procedure like a first trimester abortion?
A. Generally speaking, yes.
Q. Where does one find those definite rules and regulations for performing first trimester abortions and other, as you say, similar procedures?
A. One would review the literature. One would review what ACOG puts out, the National Abortion Federation. Sources like this would give you guidelines.
Q. Is it your position that the ACOG guidelines and standards are definite rules and regulations?
A. No. They are purely guidelines. However, medically, legally, if you deviate from them without a documented reason for your deviation, in a court of law it will be construed as malpractice.
Q. So for malpractice purposes, you believe that these guidelines and standards and other publications by ACOG are definite rules and regulations?
A. In a court of law, they are considered to be standards even though we testify -- each time I've testified, they

24 are purely guidelines. But, again, as you'll see written
25 in the chapter, you may deviate from these. As long as you

[WARD - CROSS 1123]

1 deviate and document a reasonable approach to treatment,
2 then I would defend you till hell freezes over.
3 Q. So in the medical world, these are recommendations?
4 A. Yes.
5 Q. ACOG's publications are recommendations. They're not
6 definite rules. They're recommendations of what you should
7 do and you can deviate from them if you've got a good
8 reason; is that correct?
9 A. Correct. A reasonable reason.
10 Q. A reasonable reason.
11 A. That is documented.
12 Q. That's documented.
13 A. Yes.
14 Q. And if you follow the various ACOG recommendations or
15 you deviate from them with a reasonable documented reason,
16 you would be acting within the national standard of care;
17 is that correct?
18 A. Yes.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM DEPOSITION TESTIMONY OF STANLEY K. HENSHAW
JULY 7, 1998

[HENSHAW 20]

Q. Dr. Henshaw, can you explain whether or not the need to travel limits a women's access to abortion services?
A. Yes. The farther away a woman lives from an abortion provider, the more the distance constitutes a barrier to her getting services and

[HENSHAW 21]

Henshaw
the lower the abortion rate is for the women -- the lower the probability is that she would get an abortion.
Q. And what is that opinion based on?
A. Well, there are a number of different studies that relate to this. Maybe the best study was done in Georgia, and that study found that looking at the abortion rate by individual county, the farther the county was located from the center where abortions were provided, the lower the abortion rate in that county, taking race into account.
And then the study covered a period when a new provider was established in another city and the study found that the counties near

that city then had an increase in their resident abortion rate after the new provider came into existence.

* * *

[HENSHAW 22]

Q. And how large does the travel distance need to be in order to have an effect on a women's access to abortion services?
A. Well, I would think that it's a continuum. The more the distance, the more the barrier.
There is another study that I actually participated in that looked at the relation between having to go to another county for abortions and having -- and the gestation at which abortions occurred, and we found that having to go to another county delayed women by, on average, 4.7 days.
Now, delay is related to not getting

[HENSHAW 23]

Henshaw
a service at all. If you delay beyond a certain point, the price goes up and at that point some women wouldn't be able to pay for the abortion. Beyond a certain point past that, it's impossible to find a provider of services. So anything that delays women is going to actually prevent some women from having abortions.
And when you say that delay can cause an increase in price, can you explain what you mean by that?
A. The cost of an abortion past twelve

weeks almost doubles in general and then it goes up during the second trimester past sixteen weeks. Each additional week of delay is likely to increase the price. Different abortion providers have different weeks which they raise prices but they have price jumps up through the 20's -- I mean past 20 weeks. So an abortion at 20 weeks is close to $1,000 minimum, whereas an abortion before twelve weeks is maybe $300.
Q. And does the price depend in part on whether or not the women has to obtain the abortion in a hospital facility?
A. Well, I'm talking about nonhospital.

[HENSHAW 24]

Henshaw
If she has to go to a hospital, the prices are generally much, much higher.
Q. So even without the need to go to a hospital for a later termination of pregnancy, the price does increase at various jumps as you mentioned typically?
A. Yes, it does.
Q. Do you know whether in South Carolina there is a point at which a woman is required by law to obtain an abortion in a hospital facility?
A. No, I don't know that.
Q. Do you know what the average cost of obtaining an abortion in a hospital is nationwide?
A. The last time we calculated that, it was for 1991 and the price was on the order of $1,600 on the average for a hospital abortion.
Q. And are you aware of any data that substantiates a link between the difficulty for paying for an abortion and delay in obtaining an abortion?

A. Yes. I did a study that interviewed abortion patients and found that -- well, this was a study where Medicaid had paid for abortions at the earlier time period and then stopped paying

[HENSHAW 25]

for abortions.
And we found that when Medicaid stopped paying for abortions the low-income women who were still able to pay for their own abortions got their abortions later than they had when it was covered by Medicare. That is it was free for them.
And we compared that to women who were not on Medicaid, higher income women, and the discrepancy between the low-income and higher-income women increased enormously after Medicaid stopped paying for the abortions.
Q. And do you remember what numbers were associated with those differences in obtaining abortion services for the lower and higher income women?
A. The figure I remember was that some 20 percent of the second trimester abortions obtained by these low-income women would have been in the first trimester had Medicaid continued to pay for the abortions.

* * *

[HENSHAW 27]

Q. And will the need to travel to obtain abortion cause some women not to obtain an abortion at all?

A. Undoubtedly some women would not get abortions that they would have gotten if they

[HENSHAW 28]

Henshaw
didn't need to travel.
Q. And are you aware of any effect of a decrease in the number of abortions providers on the nomber of women who are able to obtain an abortion?
A. Yes. Over the years in observing trends in abortion rates, I have noticed that when the number of providers declines, the number of abortions also declines. Now, the causal relationship in my opinion goes both directions. That where you have less demand, you may have fewer providers, but a large part of it I think is the other way. With fewer providers, you have fewer women obtaining the services.
Q. And what is that opinion based upon?
A. Well, the most striking example was in the state of South Dakota there were two providers at one point. One of the providers went out of business, so that left one provider in the state. After that the proportion of the South Dakota residents who got abortions who went out of state doubled and the abortion rate, even taking that into account, the number of women in South Carolina who were able to get abortions declined

[HENSHAW 29]

Henshaw
by, as I recall, 23 percent.
MR. OXNER: In South Dakota.
THE WITNESS: In South Dakota.

That's in South Dakota residents.
A. I have also looked at cities, metropolitan areas to see what the effect was of an increase or decrease in number of providers. And this was a long time ago, but I did a regression analysis using all of the cities in the country and just taking those where there were some providers at two time points, like 1982 and '85 or some period like that and found that where the number of providers decreased, even if there were still providers in the city, the number of abortions tended to decrease and vice versa.
Q. And based on your expertise and your experience, do you have an opinion on whether a decrease in the number of abortion providers in South Carolina might have an effect on the ability of women in South Carolina to obtain abortion services?
A. Well, in general, yes. It would depend on what kind of a decrease and what kind of providers. There may be some instances where a

[HENSHAW 30]

decrease could have no effect. For example I count as a provider a where one abortion is done. Well, if that hospital then had rules against doing abortions ever, it probably wouldn't be statistically -- I mean a significant impact on the number of abortions provided in the state. On the other hand, if a large provider stopped, I'm sure it would have an impact.

* * *

[HENSHAW 40]

Q. Are you aware of the effects of

[HENSHAW 41]

Henshaw
increased cost of abortion services and women's ability to be obtain those services?
A. Yes.
Q. And how does increased cost affect access to services generally for women?

A. Well, the most reliable statistical studies are of the effect of Medicaid stopping to pay for abortions. So this is a difference between the cost to low-income women of zero or close to zero because of just her own personal transportation expenses and the price she would have to pay to the abortion facility.
Let me remind people that most women have to pay for their abortions with cash. Insurance often usually doesn't cover abortions and women, especially low-income women don't have insurance. So the studies I am referring to are of low-income women comparing before and after the cutoff of Medicaid funding, and the best study I think is the study by Trussell, who is a demographer at Princeton, he's head of the Office of Population Research at Princeton University.

[HENSHAW 42]

Henshaw
It was done through the Alan Guttmacher Institute but it had outside authors.

That study found that between 18 and 23 percent of women who would have had Medicaid abortions instead continued their pregnancies and had births after Medicaid would no longer pay for their abortions.

There have been other studies that also had similar results. There is a recent study in North Carolina which studied the effect of the North Carolina Abortion Fund, which sometimes runs out of money before the end of the fiscal year. And the women who -- well, at the time -- you can tell what the impact of the funding is by comparing what happens to women who get pregnant during that period when the abortion fund is no longer paying for abortions compared to earlier in the year when it was paying for abortions.

They concluded that about 30 percent of women who would have their abortions paid for continued their pregnancies if there is no funding available, and there have been at least two other studies, one in Illinois and one in Texas and one

[HENSHAW 43]

Henshaw in Michigan that came to similar conclusions about the effect of cutting off Medicaid funding for abortions.

* * *

[HENSHAW 45]

Q. Based on the information that you just discussed of the surveys relating to women who could no longer received Medicaid payment and

the information from North Carolina, have you arrived at any conclusions about the extent to which an incremental increase in cost can affect a woman's ability to obtain abortion services?
A. Well, yes. If the $250 charge prevents, say, 25 percent of women -- of poor women from obtaining abortions, it seems to me it's self-evident that an increased cost would affect more women, a decreased cost would affect fewer women.
Q. And do you have an opinion as to what level of magnitude an increase of say $25 on top of the current cost for a typical first trimester abortion might have on a low-income women's ability to obtain such an abortion?
A. Well, I think by logical reasoning you can come to some very general idea of what the

[HENSHAW 46]

Henshaw
effect might be. For the first $250 each -- if you spread the $25 over the $250, you would conclude each $25 affects 2 percent of women -- let's see two and a half percent of women and 10 of those affects 25 percent of women. So if two and a half percent of women are affected by $25, at that low range, it's probably a smaller percentage at a higher range.
My guess would be $25 would affect 1 to 2 percent of women, you know, pass $200 or $300.
You can look at it another way. If you raise the price, say, to $1,000 for these poor women, probably not too many of them would get abortions at that point. Say you were optimistic and said that 20 percent could still get

abortions, that would mean that 80 percent couldn't. So the percent that couldn't get abortions would go from 25 percent to 80 percent, which is a difference of 55 percent. So raising the price, say, from $250 to $1,000 affects 55 percent of women, spread that over the $750, then you find 1 or 2 percent of women would be affected by each additional $25

[HENSHAW 47]

Henshaw

charge.

Q. So your conclusions as to the possible effect of increases in prices is based on studies that you have already discussed where there was a change in women's ability to obtain funding for abortions?

A. That's correct.

Q. And based on your experience and expertise and studies that you have reviewed or conducted, do you have an opinion as to whether increased cost might prevent some women from obtaining an abortion altogether?

A. Well, that's what I was just saying. I think any increase affects some. The question is how many. A small increase affects very few, but some.

Q. And in addition to preventing women entirely from obtaining abortions, do you have an opinion as to whether an increase in cost may cause delay in other women obtaining abortions although they ultimately do obtain the abortion services?

A. Yes. As I said, in our study in the one clinic where abortion was covered by Medicaid

[HENSHAW 48]

Henshaw
and then Medicaid stopped covering abortion, we found that women were delayed after the Medicaid payment was cut off.
There is another study that was done by the Alan Guttmacher Institute. I participated peripherally in that study of why women have abortions and why are they delayed. This was of women who had abortions at sixteen weeks or more which is fairly late.
We asked them what caused you to be late having the abortion. The most commonly mentioned reason, this is by 48 percent of the women, as I recall, was making arrangements to get the abortion and that involved transportation, getting the money together to pay for it, finding out where to go to have the abortion.
That's another bit of evidence showing that the higher the cost, the higher the financial barriers, the more women are likely to be delayed.
Q. And within that percentage of women who mentioned that difficulty of -- the difficulty in obtaining an abortion, did a particular percentage within that identify cost as a major

[HENSHAW 49]

Henshaw
factor in causing them to delay?
A. That's in the affidavit somewhere like 50 percent or 60 percent said that cost -- I would have to check that number.
Okay, 48 percent attributed all or part of the delay to difficulty making the

arrangements to get the abortion. 60 percent said they needed extra time to raise money. More than one-quarter said they could not find a provider nearby and had to arrange transportation.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM DEPOSITION TESTIMONY OF RICHARD GOODRICH DECEMBER 15, 1997

[GOODRICH 45]

Section 205-D-2, there was a question of, the registered nurse shall be on duty, and there was a question that should say, a registered nurse should be on the premises. My feeling on that was no change should be made in that, that on duty was sufficient. My feeling in that regard was an RN would have the ultimate responsibility, but would not have

[GOODRICH 46]

to necessarily be on the premises at all times.
Q. So you understood on duty -- someone could be on duty without necessarily being on the premises?
A. Yes.

* * *

[GOODRICH 83]

Q. Is it your understanding that this regulation applies to offices in which only medical abortions are performed as long as the requisite number is performed?

A. At the time we were going over this, I
didn't think about medical abortions being covered.

* * *

[GOODRICH 127]

A. You know, I do not remember discussing
that issue, medically-induced abortions, per se.
Q. Okay.
A. I might add that it would not be my intent
to include medically-induced abortions in --
Q. Within these regulations?
A. Right.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

[TITLE OMITTED IN PRINTING]

EXCERPTS FROM DEPOSITION TESTIMONY OF ROBERT A. LAWYER FEBRUARY 3, 1998

[LAWYER 61]

Q. WE TALKED A LITTLE BIT BEFORE ABOUT MEDICAL ABORTIONS.
DO YOU HAVE ANY IDEA WHAT THE TASKS OF A NURSE WOULD
BE IN AN OFFICE WHERE MEDICAL ABORTIONS WERE
PERFORMED?
A. NO, MA'AM, I DO NOT HAVE THAT KNOWLEDGE.
Q. SO YOU WOULD HAVE NO IDEA IF THOSE TASKS WOULD REQUIRE
AN R.N., AS OPPOSED TO AN L.P.N.?
A. I WOULD NOT.
Q. ARE YOU AWARE THAT THESE REGULATIONS AS WRITTEN APPLY
TO MEDICAL ABORTIONS, FACILITIES IN WHICH ONLY MEDICAL
ABORTIONS ARE PERFORMED?
A. ONLY?
Q. YES.
A. YES, MA'AM.

* * *

[LAWYER 89]

A. WELL, WAIT A MINUTE. LET ME BACK UP ON THAT. "ONE.
THERE MUST BE DOCUMENTATION OF EACH LOAD RUN DAILY."
THAT'S STANDARD MEDICAL PRACTICE. "A BIOLOGICAL TEST
OF THE AUTOCLAVE SHALL BE RUN DAILY AND THE RESULTS
MAINTAINED ON A LOG." AND THEN THE NEXT ONE IS "EACH

[LAWYER 90]

SEPARATE PACKAGE OF INSTRUMENTS TO BE STERILIZED MUST
HAVE INTERNAL AND EXTERNAL CHEMICAL INDICATORS."
THOSE ARE WHAT I WAS TALKING ABOUT THAT CHANGE COLOR.
A BIOLOGICAL TEST SHOULD BE DONE WEEKLY.
Q. THAT SHOULD BE DONE WEEKLY; O.K. YOU MEAN THERE IS A
MISTAKE HERE?
I BELIEVE THAT, YES, MA'AM. BECAUSE THE STANDARD OF
PRACTICE IS THAT THE BIOLOGICAL TEST SHOULD BE DONE
ONCE A WEEK ON AN AUTOCLAVE, AND THAT'S WHERE YOU PUT
THE SPORE, THE LIVE SPORES IN, IN A CONTAINER, AND
THEN HOPEFULLY THEY DIE.